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MEDICALLY ASSISTED PROCREATION AND THE PROTECTION OF THE HUMAN EMBRYO COMPARATIVE STUDY ON THE SITUATION IN 39 STATES

CLONING COMPARATIVE STUDY ON THE SITUATION IN 44 STATES

For the following countries, the answers in the tables have not been officially checked: **Cyprus, Hungary, Italy, Malta, Poland, Romania, Russia, San Marino, Ukraine.** Delegations to the CDBI of this countries are kindly invited to do so as soon as possible.

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I - MEDICALLY-ASSISTED PROCREATION

(M-A.P = Medically-assisted procreation)

A-General conditions of M-A.P

1-Current state of legislation, rules or practices

- 1. Is there legislation regulating M-A.P techniques? (y/n) (If not, go to question 3)
- a) What is the nature of these rules (legislation, custom, code of ethics...)?b) Please give the title of the legislation.
- 3. Is the use of the following M-A.P techniques lawful:
 - a) artificial insemination within a couple? (y/n)
 - b) in vitro fertilisation within a couple? (y/n)
 - c) artificial insemination by donor? (y/n)
 - d) ovum donation? (y/n)
 - e) ovum and sperm donation? (y/n)
 - f) embryo donation? (y/n)
 - g) intracytoplasmic sperm injection? (y/n)
- 4. Is surrogate motherhood lawful? (y/n)
- 5. If not, are there exceptions to the ban? (y/n)
- 6. Is M-A.P:
 a) freely available? (y/n)
 b) subject to conditions? (y/n)
- 7. If access to M-A.P is subject to conditions, are these conditions related to :
 a) infertility? (y/n)
 b) the risk of transmitting a disease? (y/n)
 c) other? (y/n) Please specify.

2-Medical conditions

a. Infertility

9.

- 8. Does the law stipulate that in order for someone to benefit from M-A.P, all infertility treatment methods should have failed? (y/n)
 - Is infertility : a) defined by law? (y/n) b) defined according to medical criteria? (y/n)
- 10. Is there an upper age limit after which a woman may not benefit from M-A.P? (y/n)

11. If so, please specify that age limit.

b. The risk of transmitting a disease to the child

- 12. Is the risk of transmitting a disease to the child a possible condition for access to M-A.P? (y/n)
 (if not, go to question 16)
- 13. What kind of disease allows access to M-A.P:
 a) a serious hereditary disease? (y/n)
 b) a serious disease, even if it is not hereditary? (y/n)
 c) other? (y/n) Please specify.
- 14. Is a serious disease understood to mean only a disease that would result in the early death of the child or a severe handicap? (y/n)
- 15. Must there be a serious risk of transmitting a disease? (y/n)

3-The concept of a heterosexual relationship

- 16. Is M-A.P available to an unmarried couple? (y/n) (if not, go to question 18)
- 17. If so, does the unmarried couple have to satisfy certain conditions:a) must the couple have been together a certain length of time? (y/n)b) are there other conditions? (y/n) If so, please specify.
- 18. Is M-A.P available to a woman who is not in a heterosexual relationship? (y/n)
- 19. Are the following M-A.P techniques available to a widow:
 a) transfer of an embryo fertilised when the husband was alive? (y/n)
 b) artificial insemination with the sperm of the deceased? (y/n)
 c) in vitro fertilisation with the sperm of the deceased? (y/n)
- 20. If so, is the deceased husband's prior consent necessary? (y/n)
- 21. Can a woman who is divorced or legally separated (or in the process of divorce or separation) request the implantation of an embryo fertilised by her ex-husband's sperm? (y/n)
- 22. If so, is the ex-husband consent required before implantation? (y/n)

4-The interests of the unborn child

23. Is the concept of "the well-being of the unborn child" explicitly provided for either in legislation or codes of practice governing the conditions for access to M-A.P techniques? (y/n)

- 4 -

(if not, please go on to question 26)

- 24. Which authority is responsible for assessing whether that condition is satisfied:
 a) the medical team? (y/n)
 b) a judicial body? (y/n)
 c) both successively? (y/n)
 d) other? If so, please specify.
- 25. If treatment is refused because the condition of the child's well-being is not satisfied, are reasons for the decision given? (y/n)
- 26. Is it lawful to use the various M-A.P techniques in order to choose the child's sex:a) in general? (y/n)b) in specific cases, to prevent the transmission of certain diseases? (y/n)
- 27. Is it lawful to use the various M-A.P techniques to obtain specific characteristics (other than sex) in the future child? (y/n)
- 28. If no, please give details.

5-The medical team

- 29. Is special authorisation necessary to practise M-A.P:
 a) in general? (y/n)
 b) only certain techniques? (y/n) (please specify)
 (If not, please go on to question 34)
- 30. If yes to a) or b), who issues such authorisation?
- 31. Which methods are used to refuse or grant such authorisation (visits to establishments, questionnaires, enquiries, etc)?
- 32. Does such authorisation need to be renewed periodically? (y/n)
- 33. If so, how often?
- 34. May a person working in an establishment which practises M-A.P refuse to take part for reasons of conscience? (y/n)

6-Safety measures

- 35. Are the following systematically investigated:a) the risks of transmitting a hereditary or infectious disease? (y/n)b) any other factor representing a risk to the mother or child? (y/n)
- 36. Are there rules stipulating the minimum degree of investigation to be carried out? (y/n)

- 37. Does the medical team have to keep a file on each patient so that it may check whether those rules have been observed? (y/n)
- 38. Where legislation requires to practice M-A.P can it be withdrawn if it is found that the conditions for such authorisation have not been satisfied? (y/n)
- 7-The persons concerned
- 39. Are the persons concerned informed in advance of the medical, legal and social consequences of M-A.P? (y/n)
- 40. If so, how :
 a) in person? (y/n)
 b) by an information booklet setting out the principles applicable? (y/n)
 If so, please give references.
- 41. Who is required to give their consent for M-A.P to be practised:a) the woman? (y/n)b) the husband or the partner, if there is one? (y/n)
- 42. Is such consent obtained by:a) the medical team? (y/n)b) another body? (y/n) (please specify)
- 43. Is such consent obtained:a) orally? (y/n)b) in writing? (y/n)
- 44. Are the persons concerned entitled to withdraw their consent at any time before the M-A.P is practised? (y/n)
- 45. Is M-A.P reimbursed by the State's social security system? (y/n)

B-The practice of M-A.P

1-The removal of gametes

- 46. Is it lawful, for the purposes of practising M-A.P, to remove the following from a corpse:a) sperm? (y/n)b) ova? (y/n)
- 47. Do you know if such an operation has already been carried out? (y/n)
- 48. If so, were embryos formed from these gametes? (y/n)
- 49. Is it lawful, for the purposes of practising M-A.P, to remove ovaries from a corpse? (y/n)

- 50. If so, who is required to give their consent:
 - a) the woman? (y/n)
 - b) the parents in the event of removal from an aborted foetus? (y/n)
 - c) another person? (y/n) If so, please give details.

2-Storage

a. Gametes

51. Is the possibility of depositing one's gametes for possible personal use in the future:

a) available to anyone, including a single person, who is at risk (of infertility or another hazard)? (y/n)

b) available only to couples provided that one member is at risk (of infertility or another hazard)? (y/n)

- c) available to all couples, with no conditions attached? (y/n)
- d) freely available to anyone? (y/n)
- 52. If you have answered yes to a) or b) above :a) must the person depositing his or her gametes be at risk of infertility? (y/n)b) can that person be at risk of another hazard? (y/n) If so, please specify.
- 53. If a person who has made a deposit for personal use dies, can the gametes be used:a) for another couple, provided that the deceased has given his or her prior authorisation? (y/n)b) for another couple, without the deceased person's authorization? (y/n)
 - b) for another couple, without the deceased person's authorisation? (y/n)
 - c) for other purposes (such as research)? (y/n)
- 54. Does legislation stipulate a maximum time period for storing gametes? (y/n)
- 55. If so, how long is this period?

b. Embryos

- 56. Is there a maximum number of ova that may be fertilised at any one time to ensure the success of the procreation:
 - a) at the first attempt? (y/n) (please specify)
 - b) at subsequent attempts? (y/n) (please specify)
- 57. Is it lawful to store:¹
 - a) fertilised ova after syngamy? (y/n)
 - b) fertilised ova before syngamy? (y/n)
 - c) fertilised ova, without distinction? (y/n)
- 58. Is there a maximum number of embryos that may be implanted at any one time to ensure

¹ For the attention of the consultants :

Distinction between fertilised ova before and after syngamy exists in particular in German law. In most other countries, answer may be given only to c).

the success of the procreation:

a) at the first attempt? (y/n) (please specify)

- b) at subsequent attempts? (y/n) (please specify)
- 59. Does legislation stipulate a maximum time period for storing embryos? (y/n) (if not, go to question 62)
- 60. If so, how long is this period? (y/n)
- 61. Once this period has expired, what happens to the embryos:a) are they destroyed? (y/n)b) may they be donated to another couple? (y/n)c) may they be used for research? (y/n)
- 62. Does legislation stipulate what happens to surplus embryos? (y/n)
- 63. If not, who decides what happens to surplus embryos:a) the couple? (y/n)b) the medical team? (y/n)

2-Donation

- 64. Are there conditions for donating:
 a) sperm? (y/n)
 b) ova? (y/n)
 c) embryos (in this case, "anyone" refers to the woman or the couple)? (y/n)
- 65. If so, those conditions are:
 a) the age? (y/n)
 b) the health? (y/n)
 c) other? (y/n) If so, please specify.
- 66. Is the number of children born from the gametes of any one donor limited? (y/n)
- 67. If so, what is that limit?
- 68. Is it lawful to use donations of the following for financial gain:
 a) sperm? (y/n)
 b) ova? (y/n)
 c) embryos? (y/n)
- 69. Is the donor entitled to reimbursement of expenses incurred as a result of the donation? (y/n)

- 70. May the donor:
 - a) stipulate conditions as to the destination of the donation (eg: the gametes may not be used in the same town or county)? (y/n)
 - b) choose who shall receive the donation? (y/n)
 - c) subsequently withdraw the donation (eg: if his or her marital status changes)? (y/n)
- 71. In the case of in vitro fertilisation, is ovum donation:a) allowed in general? (y/n)b) allowed only in exceptional cases? (y/n)
- 72. If ovum donation is allowed only in exceptional cases, are those cases clearly defined? (y/n)
- 73. In the case of in vitro fertilisation, is embryo donation:a) allowed in general? (y/n)b) allowed only in exceptional cases? (y/n)
- 74. If embryo donation is allowed only in exceptional cases, are those cases clearly defined? (y/n)
- 75. If so, please give details.

C - Determination of maternity and paternity (in cases of M-A.P with donor)

- 76. Generally speaking, who is considered in law as the mother of the child:a) the woman carrying the child? (y/n)b) the woman who produced the fertilised ovum? (y/n)
- 77. If it is the woman carrying the child, can the woman who donated the ovum be considered as the mother of the child in exceptional cases? (y/n) If so, please give details.
- 78. In the case of utilisation of a donor's sperm, is the husband's or partner's consent required for insemination? (y/n)
 (if not, go to question 80)
- 79. How is this consent given:
 a) orally ? (y/n)
 b) in writing? (y/n)
 c) in the presence of the medical team? (y/n)
 d) before a indicial body? (y/n)
 - d) before a judicial body? (y/n)
 - e) in the presence of the medical team and before a judicial body, in turn? (y/n)
- 80. Is a husband who has consented to M-A.P with donor considered the legitimate father of the child? (y/n) (if not, go to question 82)
- 81. If a husband who has consented to M-A.P is considered the father of the child, can he nevertheless disclaim paternity:

- 9 -

a) only if he can prove that the child was not born as a result of M-A.P? (y/n)b) in other cases? (y/n) If so, please specify.

- 82. Is a male partner who has consented to M-A.P with donor considered the legitimate father of the child:
 - a) by virtue of the act the consent? (y/n)
 - b) by a voluntary act of recognition? (y/n)
- 83. If he is not willing to take parental responsibilities is it possible to take legal proceedings against him? (y/n)
- 84. In the case of donation, is the principle of the secrecy of procreation respected? (y/n)
- 85. In the case of donation, is the principle of the secrecy of the donor's identity respected? (y/n)
- 86. Do the Courts have the power to identify the donor? (y/n)
- 87. Is access to the donor's identity possible in order to analyse a possible hereditary risk to the child? (y/n)
- 88. If the child is given information on the donor, is the donor informed? (y/n)
- 89. May a filial relationship be established between a child conceived by M-A.P and the donor of the sperm:

a) in general ? (y/n)b) only in exceptional cases? (y/n) Please specify.

- 90. May proceedings for maintenance be brought against the donor by the child? (y/n)
- 91. If the donor's identity is known, may he or she claim, in one way or another, allowances from the child ?(y/n)
- 92. Even in the absence of filial relationship, does the child have the right to request, "at an appropriate age", information on:

a) his or her conception? (y/n)

b) the identity of the biological parents? (y/n)

II - THE EMBRYO AND THE FOETUS

- 93. Is there any legislation defining the embryo or the foetus? (y/n) (if not, go to 95)
- 94. If so, could you go into details regarding this definition? (y/n)a) for the embryo?b) for the foetus?
- 95. If there is no legislation at the moment, is legislation planned? (o/n) (if so, indicate if possible in what direction it will go)

A - Diagnostic activities

96. Is there legislation governing diagnostic activities:a) on embryos in vitro? (y/n)b) on embryos in vivo or on foetuses? (y/n)

97. If so, cite the legislation? If no, are there professional codes? (y/n) Please specify.

- 98. Is there legislation controlling:a) antenatal diagnosis? (y/n)b) pre-implantation diagnosis? (y/n)
- 99. May centres performing ante-natal diagnosis:

a) practice pre-implantation diagnosis, without there being conditions attached? (\mathbf{y}/\mathbf{n})

b) practice pre-implantation diagnosis with special authorisation? (y/n)

B-Research

1-Legal framework

- 100. Does legislation require authorisation for carrying out embryo research activities? (y/n)
- 101. If authorisation is necessary, which authority is responsible for granting it? (Please specify)
- 102. If not, are there nevertheless specific conditions to be satisfied for carrying out embryo research? (y/n)
- 103. Does national legislation provide for specific sanctions in cases of violation of the principles governing embryo research? (y/n)
- 104. Are there committees responsible for overseeing embryo research? (y/n)
- 105. Are these committees multidisciplinary? (y/n)
- 106. Do the responsibilities of these committees include an ethical dimension ?(y/n)

- 107. What is the role of these committees:
 - a) to define a research approach? (y/n)
 b) to issue guidelines in the absence of or in addition to legislation? (y/n)
 c) to monitor research activities? (y/n)
 d) to issue approval of research establishments? (y/n)
 e) to inform the public (through advice or information on sterility or genetic diseases)? (y/n)
- 108. Are these committees set up:a) at national level? (y/n)b) at regional level? (y/n)c) at local level? (y/n)
- 109. If possible, please indicate their names.
- 110. With regard to the authority mentioned in question 101:a) can these committees form part of that authority? (y/n)b) are these committees separate from it? (y/n)
- 111. Are the medical teams obliged to inform the committee of the results of their work? (y/n)
- 2-Therapeutic research (in the interests of the embryo or the foetus)
- 112. Is there either legislation or codes of practice governing therapeutic research:
 a) on embryos in vitro? (y/n)
 b) on embryos in vivo? (y/n)
 c) on foetuses? (y/n)
- 113. If so, what is the legal nature of either legislation or codes of practice concerning:a) embryos in vitro?b) embryos in vivo?c) foetuses?
- 114. Is therapeutic research lawful on:a) embryos in vitro? (y/n)b) embryos in vivo? (y/n)
 - c) foetuses? (y/n)
- 115. Is embryo research lawful on:a) for all types of disease? (y/n)b) for certain types of disease? (y/n)
- 116. If you have answered yes to b), please indicate the diseases.

- 117. Is research on foetuses lawful on:a) for all types of disease? (y/n)b) for certain types of disease? (y/n)
- 118. If you have answered yes to b), please indicate the diseases.
- 119. Is it lawful to intervene for the purpose of selecting the sex of the foetus or the embryo in the case of a disease linked to the sex chromosomes? (y/n)
- 120. Is therapeutic intervention on the germ cell line:
 a) lawful in general? (y/n)
 b) prohibited in general? (y/n)
 c) lawful in exceptional cases? (y/n)
- 121. If you have answered yes to c), please give details.

<u>3-Non-therapeutic research²</u>

- 122. Is there either legislation or codes of practice governing non-therapeutic research:
 - a) on embryos in vitro? (y/n)
 - b) on embryos in vivo? (y/n)
 - c) on foetuses? (y/n)
- 123. If so, what is the legal nature of either legislation or codes of practice concerning:a) embryos in vitro?b) embryos in vivo?
 - c) foetuses?
- 124. Is non-therapeutic research lawful on:
 - a) viable embryos in vitro? (y/n)
 - b) viable embryos in vivo or viable foetuses? (y/n)
 - c) non-viable embryos in vitro? (y/n)
 - d) non-viable embryos in vivo or non-viable foetuses? (y/n)
 - e) embryos in vivo resulting from in vitro fertilisation? (y/n)
- 125. What are the criteria for the non-viability:
 - a) of an embryo?
 - b) of a foetus?
- 126. Is special authorisation necessary for carrying out research on:
 - a) viable embryos in vitro? (y/n)
 - b) non-viable embryos in vitro? (y/n)
 - c) viable embryos in vivo or viable foetuses? (y/n)
 - d) non-viable embryos in vivo or non-viable foetuses? (y/n)

 $^{^{2}}$ Non-therapeutic research means research which is not done for the direct benefit of the individual embryo concerned and likely to harm it.

- 127. In order to carry out research on dead embryos or foetuses, is it necessary to obtain:a) only the consent of the mother? (y/n)b) the consent of both parents? (y/n)
- 128. If embryo research is lawful, until what stage of the embryo's development may it be carried out:
 - a) no limit ? (y/n)
 b) up to 14 days? (y/n)³
 c) other? (y/n) Please specify.
- 129. Is it lawful to create human embryos solely for research purposes? (y/n)
- 130. May the human gametes employed in research be used to create embryos in vitro for the purpose of procreation? (y/n)
- 131. Is it lawful to modify non-pathological hereditary characteristics? (y/n)
- 132. Are the following types of genetic intervention prohibited.⁴
 - a) sex selection? (y/n)
 - b) race selection? (y/n)
 - c) the creation of chimera? (y/n)
 - d) ectogenesis (the creation of a human being in a laboratory)? (y/n)
 - e) genetic intervention on viable human embryos? (y/n)
 - f) genetic intervention on non-viable human embryos? (y/n)
 - g) the creation of identical twins? (y/n)

C-The therapeutic use of the tissue of embryos and foetuses

- 133. Is there either legislation or codes of practice governing the use of tissue obtained from:
 a) embryo in vivo? (y/n)
 b) embryo in vitro? (y/n)
 c) foetal in vivo? (y/n)
 d) foetal in vitro? (y/n)
- 134. If so, what is the legal nature of either legislation or codes of practice :a) on embryo tissue?b) on foetal tissue?
- 135. Is the use of embryo tissue lawful:a) in vivo? (y/n)b) in vitro? (y/n)

³ This period is meant to be that of the primitive streak.

⁴ The following types of genetic intervention concern *non-therapeutic research*

- 136. Is the use of foetal tissue lawful:a) in vivo? (y/n)b) in vitro? (y/n)
- 137. Is special authorisation necessary for the use of embryo or foetal tissue? (y/n)
- 138. Is termination pregnancy forbidden by law? (y/n) (if yes, go to 141)

139. If not, is termination pregnancy possible for reasons of embryo or foetal malformation or handicap? (y/n)

- 140. May the decision to terminate a pregnancy and the conditions of termination be influenced by the subsequent use of the embryo or foetus? (y/n)
- 141. Is there a requirement for the medical team terminating the pregnancy? (o/n)
- 142. Is it legally possible to keep embryos and foetuses alive artificially before removal? (y/n)
- 143. Is the pregnant woman given information about the removal, its aim and the risks involved? (y/n)
- 144. Is the woman's consent necessary for the removal of embryo material? (y/n)
- 145. May embryo tissue intended for therapeutic use be sold? (y/n)

III - CLONING

- 146. Is it legally⁵ forbidden to create human clones (embryos with the same karyotype as another embryo or a living or dead person)?
- 147. If so, is the prohibition:
 - a. general (ie for any purpose and through any technique)?
 - b. only for some purposes (cf. question N° 148)?
 - c. only for some techniques (cf. question N° 149)?
- 148. If the prohibition is limited to some purposes, is it allowed to create human clones:
 - a. for research purposes?
 - b. as a possible source of biological material (particularly tissue) which could be used for therapeutic purposes?
 - c. with a view to avoiding the transmission of a hereditary disease to the future child (for example a mitochondrial disease)?
 - d. with a view to solving problems of absolute sterility (cloning a sterile person by transferring the nucleus of a somatic cell)?
 - e. with a view to solve infertility problems and multiply the chances for pregnancy (artificial creation of twins)?
 - f. other purposes?
- 149. If the prohibition only refers to some techniques, are the following techniques prohibited:
 - a. artificial embryo split?
 - b. transfer of the nucleus of an embryonic cell?
 - c. transfer of the nucleus of a somatic cell?

¹ Please indicate if there is a specific legal provision. If so, please indicate which one and provide a French or English version of its contents.

INDEX

For the 149 questions, **YES** (**Y**) or **NO** (**N**) were the most common responses.

When we were certain as to whether regulations or legislation existed, **NR** (**not regulated**) was the response given.

NS (**not specified**) was given as a response when no information was available regarding the question.

Sometimes an asterisk (*) appears next to a response. This corresponds to a footnote at the bottom of the table. These footnotes give additional information.

A slash (/) indicates that the absence of a response was necessary, ie an answer would be meaningless.

A few responses have been left blank when we were uncertain about the legislation's effect.

Remark from Germany :

Answering the question with "yes" or "no" often gave rise to considerable problems because of the complexity of the subject-matter. Germany tried to cover the normal case when considering the answers; on the other hand, we could not go into all exceptions and sub-exceptions. The answers to the various questions in this questionnaire therefore do not entail conclusive and binding information on the German legal position.

I - MEDICALLY ASSISTED PROCREATION

- 1. Are there legislations regulating M-A.P techniques?
- a) What is the nature of these rules (legislation, custom, code of ethics...)?b) Please give the title of the legislation.]

Country	Rep.	Country	Rep.
Austria	yes*	Netherlands	yes*
Belgium	no	Norway	yes*
Bulgaria	yes*	Poland	no
Cyprus	no	Portugal	yes*
Czech Rep.	yes*	Romania	no
Denmark	yes*	Russia	yes*
Estonia	no*	San Marino	no
Finland	no	Slovakia	yes*
France	yes*	Slovenia	yes*
Germany	yes*	Spain	yes*
Greece	no*	Sweden	yes*
Hungary	yes*	Switzerland	yes*
Iceland	yes*	Turkey	yes*
Ireland	yes*	Ukraine	no
Italy	yes*	United Kingdom	yes*
Latvia	no*	Australia	yes*
Liechtenstein	no*	Canada	yes*
Lithuania	no*	New Zealand	no
Luxembourg	no*	United States	yes
Malta	no*		

- 18 -

<u>Austria</u>: The law on transplantation medicine "Fortplanzungsmedizingesetz" (FMedG) came into force on 1 July 1992.

Bulgaria: Health Ministry Order of 30 May 1987 on artificial fertilisation of women.

<u>Czech Republic</u>: The only legislative text, dating from 1982, is an Order of the Health Ministry of the Czech Socialist Republic on conditions of homologous and heterologous artificial insemination. Moreover, there is the Constitution of the Czech Republic and some international treaties concerning human rights which can be taken into account. It can be noted also the Family Code No. 1964-40 and the Law on Public Health No. 1966-20.

The assisted procreation section of the Czech Gynaecological and Obstetrics Society has formulated other principles relating more to centres performing M-A.P than to ethics. A draft Code of Ethics has been produced by the Association of Medically Assisted Procreation Centres.

<u>Denmark</u>: Act on artificial procreation in connection with medical treatment, diagnostics and research, etc... (1997).

Estonia: There is the draft Law on Artificial Fertilisation and the Protection of Human Embryo.

<u>Germany</u>: The "Embryonenschutzgesetz" (Protection of the Human Embryo Act) took effect on 1 January 1991. In October 1994 the legislator was vested with authority in respect of M-A.P and research but has not exercised it. Each medical board at the level of the "Länder" (Landesärtztekammer) draws up a code of professional ethics (Berufsordung) for M-A.P practitioners on a model (Musterberufsordnung) issued by the Federal Medical Board. They differ in the details. An appendix contains detailed rules of practice for *introduction of gametes into the fallopian tube (GIFT)* and IVF with embryo transfer. The "Adoption Procurement Act" also applies.

<u>France</u>: The following laws apply:

-No. 94-548 of 1 July 1994 on personal data processing for health research purposes.

-No. 94-653 of 29 July 1994 on respect for the human body.

-No. 94-654 of 29 July 1994 on donation and use of human body parts and derivatives, M-A.P and antenatal diagnosis.

The above are incorporated into the Civil Code, the Public Health Code and the Penal Code.

<u>Greece</u>: No actual law on M-A.P, but Law No. 2071 of 15 July 1992 on modernisation and organisation of the health system provides for setting up specialised artificial procreation units with public or private hospitals.

<u>Hungary</u>: Health Ministry Order No. 12 of 29 September 1981 on artificial insemination, supplemented by a methodological circular applicable to the National Obstetrics Institute and the National Urology Institute alike. Concerning donation of ova and sperm, reference should be made to the 1972 Health Act and the Health Ministry Order of 4 November 1972 implementing the provisions on removal and transplantation of organs and tissues. An Ethical Code drawn up by the Scientific Committee on Medical Affairs also settles a number of issues.

Iceland: Law on medically-assisted procreation, 1 June 1996 (No. 55/1996).

<u>Ireland</u>: "General Medical Council Guidelines", a guide to procedures, ethical conduct and fitness to practice.

<u>Italy</u>: The only existing regulations are constituted by a 1985 Health Ministry circular intended to regulate M-A.P as practised within the public health structures (Servizio Sanitario Nazionale). Where private health facilities are concerned, the only rules are of a purely ideological nature, such as those embodied in the self-regulation code of Italy's sperm bank CECOS (Centro per la conservazione del seme). A number of bills have been tabled. The Senate Health Commission has combined these into a single text on which it is due to deliberate. Meanwhile, the National Federation of Medical and Surgical Associations has decided to act by adopting a clause for inclusion in the new Code of Medical Ethics. This provision (Article 41) contains very strict prohibitions largely inspired by the 1994 Opinion of the National Bioethics Committee and much further-reaching than the purport of the aforementioned bill (eg prohibition of M-A.P for unmarried women and couples with an unstable relationship).

Latvia: M-A.P has been practised in Latvia since 1996. There is no official legislation on artificial procreation but a draft law is in parliamentary commission and will be discussed in the near future.

<u>Liechtenstein</u>: In 1987 the Government mandated the Criminal Law Reform Commission to draft a bill on human reproduction. This was submitted to the Government in 1988 but was not proceeded with or passed. Liechtenstein has no law or court precedent relating to M-A.P.

Lithuania: A new project of "The Law of Family Health Care" is planned to be debated at the Parliament in 1997.

<u>Luxembourg</u>: No legislation on M-A.P, but the National Advisory Committee on Ethics is preparing an opinion on the matter. A single provision of the Civil Code (Article 312) amended in 1979 makes it unlawful for a husband to disown a child conceived by artificial insemination.

Malta : M-A.P is practised in the absence of regulations.

Norway: Act relating to the Application of Biotechnology in Medicine, Chapter II.

<u>Netherlands</u>: Decree of 11 August 1988 amending the general regulations on hospital installations. New sections have been introduced to regulate laboratories producing and storing human embryos, together with ex-corpore generation of human embryos as a component of IVF treatment.

Numerous professional rules relating to M-A.P and research on embryos.

It has been decided to prepare a bill on fertilisation techniques and a proposal to amend the paternity provisions of the Civil Code.

<u>Portugal</u>: - Legislative Decree No. 319/1986 of 25 September 1985 regulating the activities of sperm banks.

- Article 1839, 3 of the Civil Code establishes that in the case of an artificial insemination with the consent of the husband, he can not disclaim paternity.

- Article 168 of the Penal Code prohibits artificial reproduction without the consent of the woman.

- Ethical rules - Code of Medical Ethics (Article 53 on artificial insemination).

- Opinions of the Portuguese National Ethics Committee (Opinion No. 3/CNECV/93 and Opinion No. 23/CNECV/97).

<u>Russia</u>: Legislative principles of the Russian Federation on protection of citizens' health of 22 July 1993, containing general provisions on procreation in Russia.

<u>Slovakia</u>: The only legislative text, dating from 1983, is a regulation of the Health Ministry of the Slovak Socialist Republic on conditions of homologous and heterologous artificial insemination. It concerns only artificial insemination, whether homologous or heterologous, to the exclusion of any other medically assisted procreation technique. In 1994 a new law on medical care came into force but contains no provisions on M-A.P.

Slovenia: - Law on medical measures allowing free choice of childbirth (1973).

- Bill on treatment of infertility and on fertilization with biomedical assistance (1997). It is expected to be passed in autumn 1997 or spring 1998.

- Ethical code in this field, entitled "Medically assisted procreation, Code of practice" (1996). It defines the current practice and largely overlaps the provisions in the Bill.

The answers to this questionnaire mainly reflect the current practice but also the provisions in the Bill which are likely to accepted.

Spain: Law on artificial procreation Act (No. 35/1988).

Law on donation and use of human embryos and foetuses, including derived tissues, cells and organs (No. 42/1988).

These two statutes are to be interpreted in conjunction with the General Health Act regulating the entire structure of the Spanish public health system.

Sweden: Swedish in Vitro Fertilisation Act (1988)

Act concerning use of gene technology on human beings and experiments on human beings with fertilised ova (1991).

<u>Switzerland</u>: M-A.P legislation rests with the cantons, which is going to change within a short period of time and 12 of the 26 cantons have passed regulations on it. Up until 1992 a text issued by the Swiss Academy of Medical Sciences (ASSM) in 1990 was authoritative, containing medical ethics guidelines for medically assisted procreation. In 1992 the nation approved at referendum a constitutional provision (Article 24 novies of the Swiss Federal Constitution) on protection of the human and the human environment against abuses relating to procreation and genetic engineering techniques. This lays the foundations for a body of legislation in preparation. A preliminary draft federal law on M-A.P setting up a National Ethics Committee has been at the consultation stage, after which a bill is being put to Parliament and is expected to be followed by other bills (on human genetic analysis and bio-medical research on humans, including research on the human germ cell line).

<u>Turkey</u>: Regulation amending the Regulation on In vitro fertilization and embryo transfer centers (Official Gazette, No. 22822 of 19 November 1996).

<u>United Kingdom</u>: Human Fertilisation and Embryology Act 1990 and Human Fertilisation and Embryology (Disclosure of Information) Act 1992. Regulations made under the 1990 Act and Code of Practice based on these statutes.

<u>Australia</u>: The States of South Australia, Victoria and Western Australia have regulated infertility treatment services. In the other states, attention should be drawn to the report on the situation of human experimentation, with additional notes, by the NHMRC (National Health and Medical Research Council).

The Infertility Act passed in 1984 and amended in 1987 was then the world's first legislation on in vitro fertilisation and experimentation with embryos. Other laws have been enacted in South

Australia and Victoria.

<u>Canada</u>: The Civil Code of Quebec has a section on medically assisted procreation. There is also a bill before the House of Commons of Canada (House Bill C-47, known as the Human Reproductive and Genetic Technologies Act), that would regulate and prohibit a number of M-A.P practices.

3. Is the use of the following M-A.P techniques lawful:

a) artificial insemination within a couple? (y/n)
b) in vitro fertilisation within a couple? (y/n)
c) artificial insemination by donor? (y/n)
d) ovum donation? (y/n)
e) ovum and sperm donation? (y/n)
f) embryo donation? (y/n)
g) intracytoplasmic sperm injection? (y/n)

Country	a		b	c	:	d	e		f	g	С	ountry	a	ı	b	c	Ċ	ł	e	f	g	Ŗ
Austria	у		у	у		n	n	n		ns	Ne	etherlands	у		у	у	у		у	у	у	
Belgium	у*		y*	y*	:	y*	у*	y*	:	y*	Ne	orway	у		у	у	n		n	n	у	
Bulgaria	*										Ро	land	*									
Cyprus	у*		у	у		у	у	у		у	Ро	ortugal	*									
CzechRep	у		у	у		у	nr	nr		у	Ro	omania	nr		nr	nr	nr	•	nr	nr	nr	
Denmark	у		у	у		у	n	n		у	Rı	issia	ns		ns	ns	ns	3	ns	ns	ns	3
Estonia	у		у	у		у	у	у		у	Sa	n Marino	nr		nr	nr	nr	•	nr	nr	nr	•
Finland	у		у	у		у	у	у		у	SI	ovakia	у*	:	у	у*	n		у	у	у	
France	у		у	у		у	n	у		у	SI	ovenia	у		у	у	у		n	n	у	
Germany	у		у	y*	:	n	**	*1	**	у	Sp	pain	у		у	у	у		у	у	у	
Greece	nr*	:	nr	nr	:	nr	nr	nr		nr	Sv	veden	у		у	у	n		n	n	у	
Hungary	у		у	у		у	у	у		ns	Sv	vitzerland	у*	:	у*	у*	n*	*	у*	n*	y*	×
Iceland	у		у	у		у	у	n		у	Тι	ırkey	у		у	ns	ns	3	ns	ns	у	
Ireland	у		у	n		n	n	n		у	U	kraine	nr		nr	nr	nr	•	nr	nr	nr	•
Italy	*										U.	Kingdom	у		у	у	у		у	у	у	
Latvia	nr		nr	nr	:	nr	nr	nr		nr	A	ıstralia	у		у	у	у		у	у	у	
Liechtest		nr		nr	nr	n	r	nr	nr		nr	Canada		у		у	у	у	,	у	у	у
Lithuania	L	nr		nr	nr	n	r	nr	nr		nr	N-Zealand		n	*	nr	nr	n	r	nr	nr	nr
Luxembr	g	nr		nr	nr	n	r	nr	nr		nr	USA		у		у	у	у	,	у	у	у
Malta		у*		y*	у	у		у	у		у							l				

Belgium: These techniques are applied although there is no relevant law.

<u>Bulgaria</u>: The Order does not itemise the various procreation techniques. It defines artificial insemination as a therapeutic procedure whereby a woman is inseminated with genetic material from her husband or from a person unknown to the couple.

Cyprus: In the absence of statutory limitations, all M-A.P techniques are lawful.

<u>Germany</u>: * There has been no legislative regulation of sperm donation yet.

** Ovum donation is prohibited.

*** According to the conception of the Protection of the Human Embryo Act embryo donation may only be considered in exceptional cases to save a so-called spare embryo.

<u>Greece</u>: In the absence of legislation, M-A.P is performed under various procedures on the basis of a consensus.

<u>Italy</u>: In the absence of a law on M-A.P, all known techniques are considered lawful and are used in practice. The 1985 circular permits only artificial insemination between partners, and prohibits fertilisation with more ova than are intended for immediate implantation.

<u>Malta</u>: In the absence of a law on M-A.P, all known techniques are considered lawful. Nonetheless, only artificial insemination and in vitro fertilisation between partners are offered in practice.

<u>Poland</u>: In the absence of laws on the subject, doctors carry out all forms of treatment but have regard to general medical and legal requirements.

<u>Portugal</u>: Legislative Decree No. 319/1986 has not yet entered into force. For this reason conditions and authorizations for techniques of medically-assisted procreation are not known and have not entered into force for the moment. Nevertheless, there is a draft law proposed on medically-assisted reproduction which can be discussed soon in the Portuguese Parliament.

Slovakia: Only artificial insemination is regulated. Doctors use other methods in practice.

<u>Switzerland</u>: A preliminary draft law interprets M-A.P as those methods inducing pregnancy outside the natural union of man and woman, without giving an exhaustive list of permissible techniques.

<u>New Zealand</u>: Although these practices are not formally regulated, they are governed by informal rules of professional practice.

4. Is surrogate motherhood lawful? (y/n)

5. If not, are there exceptions to the ban? (y/n)

Country	4	5	Country	4	5
Austria	no*	no	Netherlands	yes*	ns
Belgium	nr	/	Norway	no	no
Bulgaria	no	ns	Poland	no	no
Cyprus	yes*	/	Portugal	nr	nr
Czech Rep.	no	no	Romania	nr	nr
Denmark	no	no	Russia	no	ns
Estonia	no	no	San Marino	nr	nr
Finland	ns	ns	Slovakia	no	no
France	no	no	Slovenia	no	no
Germany	no*	ns	Spain	no*	no
Greece	nr	nr	Sweden	no	no
Hungary	yes	/	Switzerland	no*	ns
Iceland	no	no	Turkey	no	ns
Ireland	no	no	Ukraine	nr	nr
Italy	no	ns	United Kingdom	yes	/
Latvia	nr	nr	Australia	yes*	yes*
Liechtenstein	nr	nr	Canada	no*	ns
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	no*	yes**
Malta	nr*	nr			

- 25 -

<u>Austria</u>: Although there is no expressed prohibition of surrogate method, the Act seems to tend toward prohibition.

Cyprus: The surrogacy technique is lawful in the absence of statutory limitations.

<u>Germany</u>: But there is no criminal liability for surrogate mothers or for the person wishing to take the child in on a permanent basis.

Malta: There is no relevant law and there seem to be no known cases of surrogate motherhood in Malta.

<u>Netherlands</u>: The surrogacy technique is allowed but not formally authorised.

Spain: Surrogate motherhood is not expressly prohibited by law, but it is the delivery which decides maternity.

<u>Switzerland</u>: Article 24 novies paragraph 2 of the Federal Constitution, recapitulated in Article 4 of the preliminary draft. The prohibition carries a criminal penalty (Article 31 of the preliminary draft).

Australia: Generally only commercial surrogacy is prohibited.

<u>Canada</u>: Although no specific laws prohibit surrogacy contracts, they would probably not stand up in court because they violate Canadian contract and family law principles. Also, House Bill C-47 has a provision prohibiting commercial surrogacy.

<u>United States</u>: *A number of states prohibit surrogacy: Arizona, North Dakota, Kentucky, Louisiana, Michigan and Utah.

**California has not banned either commercial or non-commercial surrogacy; Arkansas, Virginia and New Hampshire have a more regulatory approach.

6. Is M-A.P:

a) freely available? (y/n)b) subject to conditions? (y/n)

7. If access to M-A.P is subject to conditions, are these conditions related to:

a) infertility? (y/n)b) the risk of transmitting a disease? (y/n)c) other ? (y/n) Please specify.

Country	6a	6 b	7 a	7 b	7 c	Country	6a	6 b	7a	7 b	7 c
Austria	n	у	у	n	n	Netherlands	n	у	у	у	n
Belgium	nr	nr	nr	nr	nr	Norway	n	у	у	у	n
Bulgaria	n	у*	у	у	n	Poland	n	у	у	n	n
Cyprus	у	n	у	n	n	Portugal	n	nr	nr	nr	nr
Czech Rep.	n	у	у	у	n	Romania	nr	nr	nr	nr	nr
Denmark	у*	у	n	n	**	Russia	у*	ns	ns	ns	ns
Estonia	у	n	/	/	/	San Marino	nr	nr	nr	nr	nr
Finland	n	у	у	у	ns	Slovakia	n	у	у	у	y*
France	n	у	у	у	у*	Slovenia	n	у*	у	у	y*
Germany	n	у	у	/	/	Spain	n	у	у	у	
Greece	у	n	n	n	n	Sweden	n	у	у	n	n
Hungary	n	у	у	у	у*	Switzerland	n	у	у	у	ns
Iceland	n	у	у	у	ns	Turkey	n	у	у	n	ns
Ireland	n	у	у	n	n	Ukraine	nr	nr	nr	nr	nr
Italy	n	у	у	ns	ns	United Kingdom	n	у	n	n	y*
Latvia	у	n	/	/	/	Australia	n	у	у*	y*	ns
Liechtenstein	nr	nr	nr	nr	nr	Canada	n	у	ns	ns	у*
Lithuania	nr	nr	nr	nr	nr	New Zealand	n	y*	ns	ns	ns
Luxembourg	nr	nr	nr	nr	nr	United States	n	у	у	у	у
Malta	n	у	у	n	n						

<u>Bulgaria</u>: The conditions differ according to whether homologous or heterologous artificial insemination is used.

<u>Denmark</u>: * Everything depends on the clinic where M-A.P is performed; access to it is unrestricted and unconditional in the private sphere but not in public medicine. Access is not limited by law.

** According to the law, artificial procreation shall be made available only to women who are married or live with a man in a de facto relationship. Furthermore artificial procreation shall not take place where the woman who is to carry and bear the child is older than 45 years of age.

<u>France</u>: In addition to the conditions which it lays down regarding the consent of those involved, the law of 29 July 1994 on bioethics restricts access to medical assistance for procreation to heterosexual couples in which the two partners are:

- alive at the time of insemination or of transfer of the embryo;
- of reproductive age;
- married or able to prove that they have been living together for at least two years.

Hungary: The age limit for women is 45 years.

Russia: All women may benefit.

<u>Slovakia</u>: Additional conditions: agreement of both partners and atrophy of the female reproductive organs.

Slovenia:

ia: - the couple must be heterosexual, with a stable relationship;

- members of the couple have to be in good general health and in appropriate psycho-social condition;
- couples with sub-normal fertility may be assisted (e.g. near end of childbearing age);
- welfare of the child must be considered.

<u>United Kingdom</u>: The welfare of the unborn child must first be considered.

Australia: See the Reproductive Technology Act 1988 (SA).

<u>Canada</u>: The 1992 Law Reform Commission Working Paper recommends that "access to medically assisted procreations should be limited only in terms of cost and scarcity. In addition, legislation governing access to medically assisted procreation should respect the right to equality". (Commonwealth Law Bulletin, July 1992, p. 281.)

<u>New Zealand</u>: In the absence of legislation, the ethical guidelines of the National Health and Research Medical Council of Australia apply.

8. Does the law stipulate that in order for someone to benefit from M-A.P, all infertility treatment methods should have failed? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	no*
Belgium	nr	Norway	no
Bulgaria	yes*	Poland	nr
Cyprus	no	Portugal	nr
Czech Rep.	yes	Romania	nr
Denmark	no	Russia	ns
Estonia	/	San Marino	nr
Finland	no	Slovakia	ns
France	no*	Slovenia	yes*
Germany	yes	Spain	yes
Greece	no	Sweden	no
Hungary	ns	Switzerland	yes*
Iceland	yes	Turkey	yes
Ireland	yes	Ukraine	nr
Italy	yes	United Kingdom	no
Latvia	no	Australia	yes
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	no
Malta	no*		

- 29 -

Bulgaria: Obligatory condition when the M-A.P method involves a third person.

<u>France</u>: Article L.152-2 of the Public Health Code stipulates only that the pathological nature of the infertility must be medically certified. Article L.152-5 of the same Code further states that only in exceptional cases a couple may receive an embryo, eg where medically-assisted procreation without the intervention of a donor can not succeed.

Malta: M-A.P is nevertheless proposed only as a last resort.

<u>Netherlands</u>: The treatment schedules may nevertheless require that certain infertility treatment methods have been unsuccessfully applied.

<u>Slovenia</u>: After reasonable measures have been made (e.g. laparoscopie, microsurgery) and proved inefficient, or when experience suggest that such treatment offers minimal prospect of success.

<u>Switzerland</u>: The preliminary draft stipulates that other treatments must have failed or offer no prospect of success.

Is infertility: 9.

a) defined by law? (y/n)b) defined according to medical criteria? (y/n)

Country	a	b	Country	a	b
Austria	ns	ns	Netherlands	no	yes
Belgium	nr	nr	Norway	no	no
Bulgaria	ns	ns	Poland	no	
Cyprus	ns	ns	Portugal	no	yes
Czech Rep.	no	yes	Romania	nr	nr
Denmark	no	yes*	Russia	ns	ns
Estonia	no	yes	San Marino	nr	nr
Finland	no	yes	Slovakia	yes	yes
France	no	yes	Slovenia	no	yes
Germany	no	yes	Spain	no	yes
Greece	no*	no	Sweden	no	yes
Hungary	no	yes	Switzerland	no	yes
Iceland	no	yes	Turkey	no	yes
Ireland	no	yes	Ukraine	nr	nr
Italy	ns	ns	United Kingdom	no	yes
Latvia	no	yes	Australia	yes*	yes
Liechtenstein	nr	nr	Canada	no	ns
Lithuania	no	yes	New Zealand	nr	ns
Luxembourg	nr	nr	United States	yes	yes
Malta	nr	nr			

<u>Denmark</u>: Infertility is indeed partly defined according to medical criteria, but personal judgment also plays a part.

Greece: M-A.P is not defined either by law or according to medical criteria.

<u>Australia</u>: The Fertility (Medical Procedures) Act 1987 (Victoria) defines infertility as the inability to conceive after twelve months of unprotected intercourse.

10. Is there an upper age limit after which a woman may not benefit from M-A.P? (y/n)

[11.	If so, please	specify that	age limit.]
L	1	1 2	0

Country	Rep.	Country	Rep.
Austria	ns	Netherlands	yes*
Belgium	nr	Norway	*
Bulgaria	ns	Poland	nr
Cyprus	nr	Portugal	nr
Czech Rep.	yes*	Romania	nr
Denmark	yes*	Russia	no
Estonia	no	San Marino	nr
Finland	no	Slovakia	non
France	yes*	Slovenia	yes*
Germany	*	Spain	no
Greece	no	Sweden	ns*
Hungary	yes*	Switzerland	yes*
Iceland	yes*	Turkey	yes*
Ireland	no	Ukraine	nr
Italy	yes*	United Kingdom	no
Latvia	no	Australia	no*
Liechtenstein	nr	Canada	nr
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	no*
Malta	no*		

<u>Czech Republic</u>: No age limit as yet, but the draft ethical code prescribes a limit at 45 years.

<u>Denmark</u>: Artificial procreation shall not take place where the woman who is to carry and bear the child is older than 45 years of age.

France: The woman (and also the man) must be of childbearing age.

<u>Germany</u>: Since ovum donation is prohibited artificial insemination with a donated ovum cannot be considered after the menopause.

<u>Hungary</u>: The age limit is 45 years.

Iceland: The age limit is 42 years with possibility up to 45 years.

<u>Italy</u>: Article 41 of the Code of Medical Ethics prohibits the performance of M-A.P on women undergoing their menopause other than prematurely (despite the existence of infringing applications to women past the age of fertility).

Malta: Absence of any age limit is demanded by the respect due to women.

Netherlands: The age limit ranges between 40 and 42 years.

Norway: No statutory age limit but a guideline sets a limit at 38 years albeit not in absolute terms.

Slovenia: The woman must be of childbearing age.

<u>Sweden</u>: There is no statutory age limit, but different guidelines in different county councils set it at between 35 and 37 years.

<u>Switzerland</u>: The couple must be of childbearing age.

<u>Turkey</u>: The woman must not be over 40 years of age.

Australia: Age must not be the reason for infertility.

United States: The state of New Hampshire has a lower age limit of 21.

Country	Rep.	Country	Rep.
Austria	no	Netherlands	yes
Belgium	nr	Norway	yes
Bulgaria	yes	Poland	nr
Cyprus	no	Portugal	nr
Czech Rep.	yes	Romania	nr
Denmark	yes	Russia	ns
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	no
France	yes*	Slovenia	yes
Germany	*	Spain	yes
Greece	no	Sweden	no
Hungary	yes	Switzerland	yes
Iceland	yes	Turkey	no
Ireland	no	Ukraine	nr
Italy	ns	United Kingdom	no
Latvia	nr	Australia	yes
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	no
Malta	no		

12. Is the risk of transmitting a disease to the child a possible condition for access to M-A.P? (y/n)

France: This is an alternative condition to that concerning the existence of a pathological infertility.

<u>Germany</u>: According to the Protection of the Human Embryo Act there is no criminal liability for choosing a sperm cell in the light of the sex chromosome contained in it if this serves the purpose of safeguarding the child against contracting a muscular dystrophy of the Duchenne type or a similarly serious sexually determined hereditary disease and if the disease with which the child is threatened has been recognised as a similarly serious disease by the agency competent to do so pursuant to Land law.

- 13. What kind of disease allows access to M-A.P:
 - a) a serious hereditary disease? (y/n)b) a serious disease, even if it is not hereditary? (y/n)c) other? (y/n)
- 14. Is a serious disease understood to mean only a disease that would result in the early death of the child or a severe handicap? (y/n)
- 15. Must there be a serious risk of transmitting a disease? (y/n)

Country	13 a	b	c	14	15	Country	13 a	b	c	14	15
Austria	/	/	/	/	/	Netherlands	у	у	n	ns*	ns
Belgium	nr	nr	nr	nr	nr	Norway	у	n	n	у	n
Bulgaria	у	ns	ns	ns	ns	Poland	nr	nr	nr	nr	nr
Cyprus	у	у	ns	ns	ns	Portugal	nr	nr	nr	nr	nr
Czech Rep.	у	ns	ns	ns	ns	Romania	nr	nr	nr	nr	nr
Denmark	у	n	n	у	у	Russia	ns	ns	ns	ns	ns
Estonia	у	n	n	у	у	San Marino	nr	nr	nr	nr	nr
Finland	у	у	ns	ns	ns	Slovakia	/	/	/	/	/
France	у*	у	n	ns	ns	Slovenia	у	у	ns	у	у
Germany	/	/	/	/	/	Spain	у	у	у	n	n
Greece	n	n	n	/	/	Sweden	/	/	/	/	
Hungary	ns*	ns	ns	ns	у	Switzerland	у*	n	у	у	у
Iceland	у	у	ns	ns	ns	Turkey	nr	nr	nr	nr	nr
Ireland	/	/	/	/	/	Ukraine	nr	nr	nr	nr	nr
Italy	ns	ns	ns	ns	ns	United Kingdom	/	/	/	/	/
Latvia	nr	nr	nr	nr	nr	Australia	у	n	ns	ns	ns
Liechtenstein	nr	nr	nr	nr	nr	Canada	nr	/	/	/	/
Lithuania	nr	nr	nr	nr	nr	New Zealand	nr	/	/	/	/
Luxembourg	nr	nr	nr	nr	nr	United States	ns	ns	ns	/	ns
Malta	nr	nr	nr	nr	nr						
France: According to the letter of the law, this must be "an illness of particular gravity".

<u>Hungary</u>: Recourse to M-A.P is permitted in the event of serious risk of transmitting a disease, without the manner of transmission being specified.

<u>Netherlands</u>: The definition of the concept of serious disease is debated.

<u>Switzerland</u>: The preliminary draft stipulates that the disease must be hereditary and incurable.

- 16. Is M-A.P available to an unmarried couple? (y/n)
- 17. If so, does the unmarried couple have to satisfy certain conditions :
 - a) must the couple have been together a certain length of time? (y/n) b) are there other conditions? (y/n)

Country	16	17a	17b	Country	16	17a	17b
Austria	yes	no	ns*	Netherlands	yes	no	yes*
Belgium	nr	nr	nr	Norway	yes	yes	yes*
Bulgaria	ns	ns	ns	Poland	no	/	/
Cyprus	no*	/	/	Portugal	nr	nr	nr
Czech Rep.	no	/	/	Romania	nr	nr	nr
Denmark	yes	no	yes*	Russia	ns	ns	ns
Estonia	yes	no	no	San Marino	nr	nr	nr
Finland	yes	ns	ns	Slovakia	yes	yes	ns
France	yes	yes*	no	Slovenia	yes	yes	yes*
Germany	yes	no	no	Spain	yes	no	no
Greece	yes	no	no	Sweden	yes	yes*	no
Hungary	yes*	ns	ns	Switzerland	yes*	no	yes**
Iceland	yes	yes*	ns	Turkey	no	/	/
Ireland	no	/	/	Ukraine	nr	nr	nr
Italy	no*	/	/	United Kingdom	yes	no	no
Latvia	yes	no	no	Australia	yes*	yes**	yes
Liechtenstein	nr	nr	nr	Canada	nr	/	/
Lithuania	nr	nr	nr	New Zealand	nr	/	/
Luxembourg	nr	nr	nr	United States	yes	ns	ns
Malta	no	/	/				

<u>Austria</u>: The case-law generally requires common domicile and finances and sexual relations between persons of opposite sex.

Cyprus: According to professional practice.

Denmark: The couple must be a man and a woman e.g. heterosexual.

France: The couple must be able to substantiate at least two years' cohabitation.

<u>Hungary</u>: According to the 1981 Order, M-A.P is available only to married couples but the Ethical Code draws no distinction.

Iceland: 3 years of cohabitation are stipulated.

Italy: Within the public health structure M-A.P is used only between spouses who are not separated.

Netherlands: Stable relationship and no addictions to alcohol and drugs etc...

Norway: The partnership must be "stable" (at least two years of cohabitation).

<u>Slovenia</u>: In practice, the requirement of "appropriate psychosocial conditions" of the couple is observed strictly.

Sweden: The law stipulates a "cohabitant" couple.

<u>Switzerland</u>: * However, only a married couple may avail itself of sperm donation. ** The well-being of the child or the couple must be of childbearing age.

Australia: * Availability depends upon the jurisdiction.

** Heterosexual de facto couples must have lived together for 5 of the previous 6 years (Western Australia).

Country	Rep.	Country	Rep.
Austria	no	Netherlands	yes
Belgium	nr	Norway	no
Bulgaria	ns	Poland	no
Cyprus	no	Portugal	nr
Czech Rep.	no	Romania	nr
Denmark	no	Russia	yes
Estonia	yes	San Marino	nr
Finland	no	Slovakia	no
France	no	Slovenia	no
Germany	/	Spain	yes*
Greece	nr	Sweden	no*
Hungary	ns	Switzerland	no
Iceland	no	Turkey	no
Ireland	no	Ukraine	nr
Italy	no	United Kingdom	yes
Latvia	yes	Australia	no
Liechtenstein	nr	Canada	yes*
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	yes
Malta	no		

<u>Spain</u>: The law states that any woman who has reached the age of 18, is in possession of full legal capacity and has given free and informed consent expressly in writing may receive or use these techniques.

<u>Sweden</u>: Donor artificial insemination and in vitro fertilisation are available only to a married or cohabiting man and woman.

<u>Canada</u>: The British Supreme Court held in Anderson v. Luoma, 14 D.L.R. 4th 749 (2 November 1984) that the Family Relations Act, R.S.B.C. 1979, c. 121, does not purport to affect the legal responsibilities which homosexuals have to each other or to children born to one of them as a result of artificial insemination.

- 42 -

19. Are the following M-A.P techniques available to a widow:

a) transfer of an embryo fertilised when the husband was alive? (y/n)b) artificial insemination with the sperm of the deceased? (y/n)

c) in vitro fertilisation with the sperm of the deceased? (y/n)

20. If so, is the deceased husband's prior consent necessary? (y/n)

Country	19 a	b	c	20	Country	19 a	b	с	.20
Austria	n	n	n	/	Netherlands	nr*	nr	nr	nr
Belgium	nr	nr	nr	nr	Norway	n	n	n	/
Bulgaria	n	n	n	/	Poland	nr	nr	nr	nr
Cyprus	n*	n	n	/	Portugal	nr	nr	nr	nr
Czech Rep.	n	n	n	/	Romania	nr	nr	nr	nr
Denmark	n	n	n	у	Russia	ns	ns	ns	ns
Estonia	n	n	n	/	San Marino	nr	nr	nr	nr
Finland	n	n	n	/	Slovakia	n	n	n	/
France	n	n	n	/	Slovenia	n	n	n	/
Germany	у	n	n	nr*	Spain	у	у	у	у*
Greece	nr	nr	nr	/	Sweden	n	n	n	/
Hungary	ns	ns	ns	ns	Switzerland	у*	n	n	
Iceland	n	n	n	/	Turkey	ns	ns	ns	ns
Ireland	n	n	n	/	Ukraine	nr	nr	nr	nr
Italy	n	n	n	/	United Kingdom	у	у	у	у
Latvia	nr	nr	nr	nr	Australia	у*	ns	ns	ns
Liechtenstein	nr	nr	nr	nr	Canada	nr	nr	nr	nr
Lithuania	nr	nr	nr	nr	New Zealand	nr	nr	nr	nr
Luxembourg	nr	nr	nr	nr	United States	ns	ns*	ns	ns
Malta	n	n	n	/					

<u>Cyprus</u>: According to professional practice.

<u>Germany</u>: Transfer of the embryo is permitted because it serves the purpose of saving its life. A person who wittingly performs artificial insemination with a deceased donor's sperm is liable to three years of imprisonment. The woman involved incurs no penalty.

Netherlands: Post mortem insemination is a subject of debate.

<u>Spain</u>: In an official document or a will, the husband must validly consent to the use of his "reproductive material" during a period of 6 months before death.

<u>Switzerland</u>: It is forbidden to use the gametes or the fertilised ova of a person after death, but the preliminary draft does not rule out exceptional cases where the preservation of the life of the embryo justifies its transfer shortly after the father's death.

<u>Australia</u>: A Tasmanian judge held that a frozen embryo is legally entitled to inherit its father's estate, even if implanted in the mother's womb after the father dies. (In the Matter of Estate of the Late K, In the Supreme Court of Tasmania, Hobart, 26 February 1996.)

<u>United States</u>: A California leading case dealt with the artificial insemination of a deceased man's sperm into his surviving girlfriend (Estate of Kane).

- 21. Can a woman who is divorced or legally separated (or in the process of divorce or separation) request the implantation of an embryo fertilised by her ex-husband's sperm? (y/n)
- 22. If so, is the ex-husband consent required before implantation? (y/n)

Country	21	22	Country	21	22
Austria	no	/	Netherlands	nr	nr
Belgium	nr	nr	Norway	no	/
Bulgaria	ns	ns	Poland	nr	nr
Cyprus	ns	ns	Portugal	nr	nr
Czech Rep.	no	/	Romania	nr	nr
Denmark	no	/	Russia	ns	ns
Estonia	yes*	yes*	San Marino	nr	nr
Finland	no	/	Slovakia	no	/
France	no	/	Slovenia	no	/
Germany	/	/	Spain	no	/
Greece	nr	nr	Sweden	no	/
Hungary	nr	nr	Switzerland	ns	ns
Iceland	no	/	Turkey	no	/
Ireland	ns	ns	Ukraine	nr	nr
Italy	ns	ns	United Kingdom	yes*	yes*
Latvia	nr	nr	Australia	no	/
Liechtenstein	nr	nr	Canada	nr	/
Lithuania	nr	nr	New Zealand	nr	/
Luxembourg	nr	nr	United States	ns*	ns*
Malta	no	/			

- 45 -

Estonia: According to the draft law.

<u>United Kingdom</u>: Once consent is given it continues until revoked; it does not automatically end with divorce or separation.

<u>United States</u>: A California leading case dealt with the artificial insemination of a deceased man's sperm into his surviving girlfriend (Estate of Kane).

- 23. Is the concept of "the well-being of the unborn child" explicitly provided for either in legislation or codes of practice governing the conditions for access M-A.P techniques? (y/n)
- 24. Which authority is responsible for assessing whether that condition is satisfied:

a) the medical team? (y/n)b) a judicial body? (y/n)c) both successively? (y/n)d) other ?

Country	23	24 a	b	c	d	Country	23	24 a	b	c	d
Austria	n	/	/	/	/	Netherlands	у*	у	n	n	n
Belgium	nr	nr	nr	nr	nr	Norway	n	/	/	/	/
Bulgaria	n	/	/	/	/	Poland	nr	nr	nr	nr	nr
Cyprus	у	у	n	n	n	Portugal	n	nr	nr	nr	nr
Czech Rep.	n*	у	n	n	n	Romania	nr	nr	nr	nr	nr
Denmark	n	/	/	/	/	Russia	ns	ns	ns	ns	ns
Estonia	n	/	/	/	/	San Marino	nr	nr	nr	nr	nr
Finland	n	/	/	/	/	Slovakia	у	у	у	ns	ns
France	n	/	/	/	/	Slovenia	у	у	n	n	n
Germany	n	/	/	/	/	Spain	n*	/	/	/	/
Greece	n	/	/	/	/	Sweden	n	/	/	/	/
Hungary	ns	ns	ns	ns	ns	Switzerland	у	у	n	n	n
Iceland	у	у	n	n	n	Turkey	n	/	/	/	/
Ireland	у	n	*	n	n	Ukraine	nr	nr	nr	nr	nr
Italy	ns	ns	ns	ns	ns	United Kingdom	у	у	n	n	ns
Latvia	nr	nr	nr	nr	nr	Australia	n*	/	/	/	/
Liechtenstein	nr	nr	nr	nr	nr	Canada	/	/	/	/	/
Lithuania	nr	nr	nr	nr	nr	New Zealand	nr	/	/	/	/
Luxembourg	nr	nr	nr	nr	nr	United States	ns*	/	/	/	/
Malta	nr	nr	nr	nr	nr						

<u>Czech Republic</u>: The medical team bears sole responsibility for ascertaining whether the interest of the unborn child is upheld.

Ireland: In the event of contestation, the case can be taken to court.

Netherlands: This concept is embodied in the various professional codes.

Spain: The law refers to the child's interest but does not treat it as a condition of access to M-A.P.

<u>Australia</u>: The Reproductive Technology Act 1988 (South Australia) mentions "the welfare of any child to be born in consequence of an artificial fertilisation procedure must be treated as of paramount importance".

<u>United States</u>: The best interest of the "born" child is of primary concern in many jurisdictions.

Country	Rep.	Country	Rep.
Austria	ns	Netherlands	yes
Belgium	nr	Norway	/
Bulgaria	ns	Poland	nr
Cyprus	yes	Portugal	nr
Czech Rep.	yes	Romania	nr
Denmark	/	Russia	ns
Estonia	/	San Marino	nr
Finland	/	Slovakia	yes
France	/	Slovenia	yes*
Germany	/	Spain	/
Greece	/	Sweden	/
Hungary	ns	Switzerland	ns
Iceland	yes*	Turkey	ns
Ireland	*	Ukraine	nr
Italy	ns	United Kingdom	yes*
Latvia	nr	Australia	/
Liechtenstein	nr	Canada	/
Lithuania	nr	New Zealand	/
Luxembourg	nr	United States	/
Malta	nr		

<u>Iceland</u>: If the physical refuses to give treatment the couple can appeal his decision to a committee appointed by Minister of Health. The committee consists of three persons, a lawyer, a physician and a social worker. The committee's decision is final.

Ireland: The situation has not arisen as yet.

<u>Slovenia</u>: When appropriate according to judgment of the medical team.

<u>United Kingdom</u>: In principle.

- 26. Is it lawful to use the various M-A.P techniques in order to choose the child's sex:
 - a) in general? (y/n)b) in specific cases, to prevent the transmission of certain diseases? (y/n)
- 27. Is it lawful to use the various M-A.P techniques to obtain specific characteristics (other than sex) in the future child? (y/n)
- [28. If no, please give details.]

Country	26a	26b	27	Country	26a	26b	27
Austria	no*	no	no	Netherlands	no	yes	no
Belgium	nr	nr	nr	Norway	no	yes	no
Bulgaria	no	no	no	Poland	no*	no	no
Cyprus	no	yes	no	Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	no	yes	no*	Russia	ns	ns	ns
Estonia	no	yes	yes	San Marino	nr	nr	nr
Finland	yes	yes	ns	Slovakia	no	no	no
France	no	yes	no	Slovenia	no	yes	no*
Germany	no	yes	no*	Spain	no	yes	no
Greece	nr	nr	nr	Sweden	ns	yes	nr
Hungary	no	yes	ns	Switzerland	no	yes	yes
Iceland	no	yes	no	Turkey	no	no	no
Ireland	no	no	no	Ukraine	nr	nr	nr
Italy	no	yes	ns	United Kingdom	no*	yes	yes*
Latvia	nr	nr	nr	Australia	no	yes*	ns
Liechtenstein	nr	nr	nr	Canada	yes*	ns	ns
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	ns*	ns	ns
Malta	no	no	ns				

- 51 -

<u>Austria</u>: Sperm and viable cells may be examined and processed only within the necessary limits of the most advanced medical science and experience for the purpose of inducing a pregnancy.

<u>Denmark</u>: In the case of artificial insemination with sperm from a donor, it is lawful to seek physically resemblance between the future child and its parents.

Germany: The Protection of the Human Embryo Act prohibits artificial changes in germ line cells.

<u>Poland</u>: One condition of antenatal diagnosis is that there should be no selection of sex or of any other characteristic.

Slovenia: This is prohibited by the Bill on gene technology.

<u>United Kingdom</u>: Lawful in the case of gamete donation to ensure compatibility with the recipient's characteristics, and in the case of pre-implantation diagnosis to avert specific diseases.

Australia: Couples who risk transmitting a sex-linked genetic disease may determine the sex of the embryo.

<u>Canada</u>: Health Minister Diane Marleau has called for an outright ban of sex selection for non-medical reasons (Toronto Star, 20 August 1996).

United States: It is unlawful in at least two States to procure an abortion based on the foetus's sex.

29. Is special authorisation necessary to practise M-A.P:

a) in general? (y/n)b) only certain techniques? (y/n)

- [30. If yes to a) or b), who issues such authorisation?]
- [31. Which methods are used to refuse or grant such authorisation (visits to establishments, questionnaires, enquiries, etc)?]
- 32. Does such authorisation need to be renewed periodically? (y/n)
- [33. If so, how often?]

Country	29a	29b	32	Country	29a	29b	32
Austria	yes*	no	yes	Netherlands	no	yes*	yes*
Belgium	nr	nr	nr	Norway	yes	no	yes*
Bulgaria	yes*			Poland	yes		
Cyprus	no*	no	/	Portugal	yes*	no	nr
Czech Rep.	no	yes*	yes*	Romania	nr	nr	nr
Denmark	no	no	/	Russia	yes*	ns	ns
Estonia	no	yes	no*	San Marino	nr	nr	nr
Finland	no	no	/	Slovakia	yes	no	no
France	yes	no	yes*	Slovenia	yes	no*	yes
Germany	no	yes	no	Spain	yes*	/	*
Greece	no	no	/	Sweden	yes*	no	nr
Hungary	yes*	no	no	Switzerland	no	yes*	yes
Iceland	yes*	no	no	Turkey	yes	no	yes*
Ireland	no	ns	ns	Ukraine	nr	nr	nr
Italy	no*	no	ns	United Kingdom	no	yes	yes*
Latvia	no	yes*	yes**	Australia	yes	no	ns
Liechtenstein	nr	nr	nr	Canada	ns	ns	ns
Lithuania	nr	nr	nr	New Zealand	nr*	nr	nr
Luxembourg	nr	nr	nr	United States	no	yes	yes*
Malta	no	no	/				

<u>Austria</u>: M-A.P may be performed solely by a gynaecologist authorised to practice, and in an approved hospital. Homologous artificial insemination, however, can be carried out by a private practitioner. Permission for artificial insemination has to be requested from the head of the provincial government ("Landeshauptmann"). Permission to use the other techniques is granted if the staff and technical facilities are such as to guarantee that the M-A.P will be carried out according to the most advanced scientific technology. The hospital or doctor must submit an annual report to the government of the province where they operate, to contain information on the techniques applied, the frequency of their application, their success rate, and the storage and use of donated sperm and viable cells.

<u>Bulgaria</u>: Artificial insemination can be carried out only by an obstetrics and gynaecology specialist in charge of a consultation centre, unit or department for the control of sterility.

<u>Czech Republic</u>: Specific authorisation is required for *FIVETE* and *ICSI*. The authorisation, issued by the Assisted Procreation Section of the Czech Gynaecology and Obstetrics Society, must be renewed annually.

Cyprus: No statutory limitations.

Estonia: Authorisation is granted by the Bioethics Committee of the University of Tartu, after investigation.

<u>France</u>: Authorisation valid for 5 years is granted after consultation of the National Commission for Reproductive Medicine and Biology and Prenatal Diagnosis and the National Health and Welfare Organising Committee. Each clinic must submit an annual progress report to the Minister for Health, and also keep registers of the gametes and embryos which it stores.

Hungary: Authorisation is granted by the Minister of Social Affairs.

Iceland: Authorisation is granted by the Minister for Health.

<u>Italy</u>: The bill nevertheless provides that M-A.P can be performed only in public or private clinics authorised to do so by the Minister for Health. It further provides for the introduction of a national register of authorised clinics.

Latvia: *Health Care Department of County. **5 years.

<u>Netherlands</u>: The Health Ministry issues authorisations to clinics performing IVF. The requirements for authorisation include assessment of professional quality and needs evaluation (a variety of planning). Authorisation is renewed every 5/6 years.

<u>Norway</u>: Authorisation is given by the National Board of Health. An annual report is drawn up as a basis for granting or refusing permission.

<u>Portugal</u>: Authorisation is not required, however, for matrimonial M-A.P performed with fresh sperm. M-A.P activities can be carried out only under the supervision and direct responsibility of a doctor in a public or private clinic approved by the Health Ministry. The Legislative Decree provides that the conditions of authorisation and the sanctions, if any, shall be determined by a subsequent decree.

Russia: M-A.P can be performed only in licensed medical clinics.

<u>Slovenia</u>: Authorizations are given by the Minister of Health, upon recommendation of an Advisory Committee on MAP, which decide for its length. These authorizations are based on site visits and proof of the professional qualifications. Presently, only units at two university departments of gynaecology are licensed. In the future, certain centers may be licensed only for some techniques.

<u>Spain</u>: All centres providing M-A.P and those carrying out collection, storage and distribution of human biological material are subject to the provisions of the General Health Act and to the administrative regulations governing competence in the field of health issued by the Health Ministry and other competent authorities (section 18 of Law No. 35/1988). The law provides that teams performing M-A.P must be specially qualified in this field, its further applications and its scientific derivations, and be in possession of the necessary equipment. They must act under the direct supervision of the head of the centre concerned (Article 19).

All approved centres and departments are inspected and supervised by the competent health authorities, who may suspend licenses when the regulations cease to be observed.

<u>Sweden</u>: Specific qualifications are required to carry out M-A.P. Donor artificial insemination is possible only in a public hospital. If in vitro fertilisation is performed in the private sector, permission must be granted by the National Board of Health and Welfare. The procedures for refusing or granting authorisation are not regulated, nor is renewal of authorisation, which is part of the Board's general supervisory activities.

<u>Switzerland</u>: Any person performing M-A.P or storing gametes must hold cantonal authorisation, but homologous insemination is not subject to authorisation.

Any person holding authorisation must submit an annual progress report, and the authorising body makes inspections without notice in the authorised centres.

<u>Turkey</u>: The term of authorisation is not specified, nor by whom it should be issued. It may be withdrawn if the relevant conditions are no longer met.

<u>United Kingdom</u>: Authorisation is given by the Human Fertilisation and Embryology Authority. Any procedure may be used to refuse or grant authorisation. The authorisation must be renewed every 3 to 15 months depending on the circumstances.

<u>New Zealand</u>: There exists a voluntary accreditation by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia.

<u>United States</u>: Such authorisation pertains to embryo laboratories as outlined in the Fertility Success Rate and Certification Act of 1992.

34.	May a person working in an establishment which practises M-A.P refuse to take part for reasons
	of conscience? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	yes
Belgium	ns	Norway	no
Bulgaria	ns	Poland	ns
Cyprus	yes	Portugal	yes
Czech Rep.	ns	Romania	nr
Denmark	yes	Russia	ns
Estonia	yes	San Marino	nr
Finland	ns	Slovakia	ns
France	no	Slovenia	yes
Germany	yes	Spain	yes
Greece	nr	Sweden	no
Hungary	ns	Switzerland	ns
Iceland	yes*	Turkey	no
Ireland	yes	Ukraine	nr
Italy	ns	United Kingdom	yes
Latvia	nr	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	ns*
Malta	yes		

Iceland: According to the Medical Act No. 53/1988.

<u>United States</u>: Although conscience clauses with regard to abortions are somewhat common, conscience clauses with regard to M.-A.P. are less so.

35. Are the following systematically investigated:

a) the risks of transmitting a hereditary or infectious disease? (y/n) b) any other factor representing a risk to the mother or child? (y/n)

Country	а	b	Country	a	b
Austria	ns	ns	Netherlands	yes	yes
Belgium	ns	ns	Norway	no	no
Bulgaria	ns	ns	Poland	ns	ns
Cyprus	yes	yes	Portugal	nr	nr
Czech Rep.	ns	ns	Romania	nr	nr
Denmark	yes	yes	Russia	ns	ns
Estonia	yes	yes	San Marino	nr	nr
Finland	yes	ns	Slovakia	yes	yes
France	yes	yes	Slovenia	yes	yes
Germany	no	no	Spain	no*	no*
Greece	nr*	nr*	Sweden	ns	ns
Hungary	yes	no	Switzerland	ns	ns
Iceland	ns	ns	Turkey	ns	ns
Ireland	yes	yes	Ukraine	nr	nr
Italy	ns	ns	United Kingdom	yes	yes
Latvia	yes	yes	Australia	yes	ns
Liechtenstein	nr	nr	Canada	ns	ns
Lithuania	no	no	New Zealand	ns	ns
Luxembourg	nr	nr	United States	no*	no
Malta	yes				

- 58 -

<u>Greece</u>: Not regulated, but in medical practice, as doctors themselves claim, such investigations are being carried out.

Spain: Spanish legislation requires that, only for donors, systematic investigations shall be performed.

<u>United States</u>: The Fertility Clinic Success Rate and Certification Act of 1992 states that there may be no regulations, standards or requirements that have the effect of exercising supervision or control over the practice of medicine in assisted reproduction technology programmes.

- 59 -

- 36. Are there rules stipulating the minimum degree of investigation to be carried out? (y/n)
- Does the medical team have to keep a file on each patient so that it may check whether those rules 37. have been observed? (y/n)
- Where legislation requires authorisation to practice M-A.P can it be withdrawn if it is found that 38. the conditions for such authorisation have not been satisfied? (y/n)

Country	36	37	38	Country	36	37	38
Austria	ns	yes*	yes	Netherlands	yes	ns	yes
Belgium	non	ns	ns	Norway	no	no	yes
Bulgaria	ns	ns	ns	Poland	ns	ns	ns
Cyprus	yes	yes		Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	yes	yes		Russia	ns	ns	ns
Estonia	no	no	ns	San Marino	nr	nr	nr
Finland	no	yes		Slovakia	yes	yes	yes
France	yes	yes	yes	Slovenia	yes*	yes	yes
Germany	no	/	no	Spain	no*	no*	yes
Greece	no	nr	/	Sweden	ns	yes	yes
Hungary	ns	yes	ns	Switzerland	ns	yes	yes*
Iceland	ns	ns	ns	Turkey	nr	nr	yes
Ireland	yes*	yes	yes	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	yes*	yes	yes
Latvia	nr	nr	nr	Australia	yes	yes	yes
Liechtenstein	nr	nr	nr	Canada	ns	ns	nr
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	no*	no	ns
Malta	nr	nr	nr				

<u>Austria</u>: § 19 FMedG requires hospitals or doctors carrying out M-A.P to report annually to the provincial government about their activities and experiences. The reports must contain data on the techniques applied, their frequency and success rate, as well as data on storage and use of donated sperm and viable cells.

Ireland: In hospitals alone.

Slovenia: They are defined by the Code of practice.

Spain: Only for donors.

<u>Switzerland</u>: The provisions governing the grant and withdrawal of authorisation will be the subject of a subsequent Order.

United Kingdom: For certain forms of treatment.

<u>United States</u>: The Fertility Clinic Success Rate and Certification Act of 1992 states that there may be no regulations, standards or requirements that have the effect of exercising supervision or control over the practice of medicine in assisted reproduction technology programs.

39. Are the persons concerned informed in advance of the medical, legal and social consequences of M-A.P? (y/n)

40. If so, how:

a) in person? (y/n)

b) by an information booklet setting out the principles applicable? (y/n)

Country	39	40a	40b	Country	39	40a	40b
Austria	yes	yes	no	Netherlands	yes	yes	ns*
Belgium	yes*	ns	ns	Norway	yes	yes	yes*
Bulgaria	yes	ns	ns	Poland	yes	ns	ns
Cyprus	no	ns	ns	Portugal	nr	nr	nr
Czech Rep.	yes*	yes	no	Romania	nr	nr	nr
Denmark	yes	yes	yes	Russia	yes	ns	ns
Estonia	yes	yes	no	San Marino	nr	nr	nr
Finland	yes	yes	ns	Slovakia	yes*	yes	no
France	yes	yes	yes*	Slovenia	yes	yes	yes
Germany	yes	yes	no	Spain	yes	ns	ns
Greece	nr	/	/	Sweden	yes	yes	yes
Hungary	yes	yes	no	Switzerland	yes*	yes	yes
Iceland	yes	yes	ns	Turkey	yes	yes	no
Ireland	yes	yes	yes*	Ukraine	nr	nr	nr
Italy	yes*	yes	ns	United Kingdom	yes	yes	yes*
Latvia	yes	yes	ns	Australia	yes	yes	yes
Liechtenstein	nr	nr	nr	Canada	ns	/	/
Lithuania	nr	nr	nr	New Zealand	nr	/	/
Luxembourg	nr	nr	nr	United States	yes	yes	ns
Malta	yes*	ns	ns				

<u>Belgium</u>: According to medical practice, the woman, and in some cases her partner, must present a request to be informed of all its medical, genetic, legal and social aspects of the M-A. P and of possible risks to themselves and to the unborn children.

<u>Czech Republic</u>: For artificial insemination with donor, the recipient couple must sign a document certifying that information has been supplied.

<u>France</u>: For medically-assisted procreation requiring the intervention of an outside donor, the judge or the solicitor (*notaire*) responsible for recording consent must provide the persons involved with information about the legal consequences of their decision.

Ireland: There are also specialised counselling services.

<u>Italy</u>: Under the CECOS regulations, the couple must receive detailed information on the technique adopted and the prospects of success in the light of worldwide and European statistics and information on the centre. They must be informed of, and certify that they accept, the possible risks of the technique.

Malta: The social consequences are nevertheless indistinct.

<u>Netherlands</u>: A handbook is in preparation.

Norway: The information booklet is available in Norwegian only.

<u>Slovakia</u>: For artificial insemination with donor, the recipient couple must certify that they have been informed of its consequences by signing a document.

<u>Switzerland</u>: The couple is also informed of "other life options and other ways of fulfilling the wish for a child".

<u>United Kingdom</u>: A memorandum of the Human Fertilisation and Embryology Authority requires approved clinics to supply their patients with written information.

41. Who is required to give their consent for M-A.P to be practised:

a) the woman? (y/n)

b) the husband or the partner, if there is one? (y/n)

Country	а	b	Country	a	b
Austria	yes	yes	Netherlands	yes	yes
Belgium	yes*	yes	Norway	yes	yes
Bulgaria	yes	yes*	Poland	yes	yes
Cyprus	yes	yes*	Portugal	yes*	yes
Czech Rep.	yes	yes	Romania	nr	nr
Denmark	yes	yes	Russia	yes	yes
Estonia	yes	yes	San Marino	nr	nr
Finland	yes	yes	Slovakia	yes	yes
France	yes	yes	Slovenia	yes	yes
Germany	yes	yes	Spain	yes	yes
Greece	nr*	nr*	Sweden	yes	yes
Hungary	yes	yes	Switzerland	yes	yes
Iceland	yes	yes	Turkey	yes	ns
Ireland	yes	yes	Ukraine	nr	nr
Italy	yes	yes	United Kingdom	yes	no*
Latvia	yes	yes	Australia	yes	yes
Liechtenstein	nr	nr	Canada	ns	ns
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	yes	yes
Malta	yes	yes			

<u>Belgium</u>: According to medical practice, the woman, and where appropriate her husband or partner, must make a written request for M-A.P.

<u>Bulgaria</u>: The couple's consent is required in case of artificial insemination with a third person's genetic material.

<u>Cyprus</u>: There is no relevant law but, according to medical practice, a donor's sperm is not used until the medical team receives the husband's or partner's permission.

<u>Greece</u>: According to medical practice.

<u>Portugal</u>: According to the Penal Code, the consent of the woman who is inseminated shall be obtained. The Civil Code requires implicitly the consent of the husband of the woman who is inseminated.

<u>United Kingdom</u>: The husband's or partner's consent is recommended though not required by law. The legal consequences in respect of paternity of the unborn child will be different if the partner has not consented. 42. Is such consent obtained by:

a) the medical team? (y/n)b) another body? (y/n)

43. Is such consent obtained:

a) orally? (y/n) b) in writing? (y/n)

Country	42a	b	43a	b	Country	42a	42b	43a	b
Austria	yes	yes*	no	yes	Netherlands	yes	no	yes	yes
Belgium	ns	ns	no	yes	Norway	yes	no	no	yes
Bulgaria	ns	ns	no	yes	Poland	yes*	no	yes	yes
Cyprus	yes	no	no	yes	Portugal	nr	nr	nr	nr
Czech Rep.	yes	no	no	yes	Romania	nr	nr	nr	nr
Denmark	yes	no	yes	yes	Russia	ns	ns	ns	ns
Estonia	yes	no	yes	yes	San Marino	nr	nr	nr	nr
Finland	yes	no	yes	ns	Slovakia	yes	ns	no	yes
France	yes*	yes*	no	yes*	Slovenia	yes	no	no	yes
Germany	yes	no	no	yes	Spain	yes	no	no	yes
Greece	yes	ns	yes	yes	Sweden	yes	ns	no	yes
Hungary	yes	no	no	yes	Switzerland	yes*	ns	no	yes
Iceland	yes	ns	ns	yes	Turkey	yes	no	no	yes
Ireland	yes	ns	no	yes	Ukraine	nr	nr	nr	nr
Italy	yes*	ns	no	yes	United Kingdom	yes	ns	yes	yes
Latvia	yes	ns	ns	yes	Australia	yes	no	yes	yes
Liechtenstein	nr	nr	nr	nr	Canada	ns	ns	ns	ns
Lithuania	nr	nr	nr	nr	New Zealand	nr	nr	nr	nr
Luxembourg	nr	nr	nr	nr	United States	yes	no	yes	yes
Malta	ns	ns	no	yes					

- 66 -

<u>Austria</u>: Consent is received by the medical authority where the couple is married, otherwise consent must be given before a court or a notary; this applies even to married couples in case of a sperm donation.

<u>France</u>: Before any insemination or attempt to transfer embryos, the couple benefiting from medicallyassisted procreation must give their consent to the medical team responsible for the operation, whether it is being carried out within the couple or with the gametes of a third party. Moreover, in the event of medically-assisted procreation involving a donor, the consent of both members of the recipient couple must also be recorded before a judge or a solicitor (*notaire*), who must notify the persons involved of the consequences of their decision, particularly with regard to filial links.

In addition, the written consent of both members of the donor couple is required for donations of gametes or renouncement of embryos by the couple (of whom they come from).

<u>Italy</u>: The declaration must be as detailed as possible to guard against any possible contestation. The couple is also required to state its acceptance of the risks entailed by the technique to be used (Article 7 of the CECOS regulations). (The bill provides that written consent is not to be given earlier than a fortnight before or later than six months after transmission of the written report provided for in the same bill).

<u>Poland</u>: In case of homologous artificial insemination, the doctors are responsible for obtaining the consent of both spouses. Use of the sperm for any other purpose than to enable the husband to inseminate his wife is regarded as a direct breach of medical ethics.

In the event of donor artificial insemination, the doctor's duty is to obtain the husband's consent to the treatment. The husband is asked to consider all possible implications for the child's welfare in the family before consenting. It has been suggested that the new legislation should deal with this question in detail to guard against any confusion.

<u>Switzerland</u>: The couple's consent must be reiterated at each menstrual cycle.

44.	Are the persons	concerned	entitled	to	withdraw	their	consent	at	any	time	before	the	M-A.P
	practised? (y/n)												

is

Country	Rep.	Country	Rep.
Austria	yes*	Netherlands	yes
Belgium	yes	Norway	yes
Bulgaria	ns	Poland	ns
Cyprus	ns	Portugal	nr
Czech Rep.	yes	Romania	nr
Denmark	yes	Russia	ns
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	yes
France	yes	Slovenia	yes
Germany	yes	Spain	yes
Greece	yes	Sweden	yes
Hungary	yes	Switzerland	yes
Iceland	yes	Turkey	yes
Ireland	yes	Ukraine	nr
Italy	ns	United Kingdom	yes
Latvia	yes	Australia	yes
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	yes
Malta	yes		

<u>Austria</u>: There are no specific formalities attaching to withdrawal of consent, but the hospital must take written note and issue confirmation on request.

45.	Is M-A.P reimbursed by	the State's social	security system? (y/n)

Country	Rep.	Country	Rep.
Austria	no	Netherlands	yes
Belgium	yes*	Norway	yes*
Bulgaria	no	Poland	ns
Cyprus	ns	Portugal	yes*
Czech Rep.	yes*	Romania	yes
Denmark	yes*	Russia	ns
Estonia	no	San Marino	nr
Finland	yes	Slovakia	yes*
France	yes*	Slovenia	yes*
Germany	yes*	Spain	yes
Greece	yes*	Sweden	yes*
Hungary	yes*	Switzerland	no
Iceland	yes*	Turkey	no
Ireland	no*	Ukraine	nr
Italy	yes*	United Kingdom	*
Latvia	no	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	no	New Zealand	ns
Luxembourg	nr	United States	yes*
Malta	yes*		

<u>Czech Republic</u>: Only some social security systems reimburse M-A.P and then only for 2 reproductive cycles.

<u>Belgium</u>: These techniques are partly financed by health insurance. A certain number of non- refundable expenses will need to be paid by the patient and these expenses vary according to the techniques used.

Denmark: Only as applied in the public sector. M-A.P performed in a private clinic is not covered.

France: Article L. 164-1 of the Social Security Code provides for reimbursement of 4 IVF trials.

Germany: But not all measures.

Greece: M-A.P is only partially reimbursed - when certain conditions are met.

Hungary: Reimbursement up to the 3rd trial.

Iceland: The couple pays part of the costs in a ratio determined by the Minister.

Ireland: The costs are nevertheless tax-deductible.

Italy: M-A.P is partly reimbursed by the health insurance when performed within the public system.

Malta: Only where performed in public hospitals. Private sector M-A.P is not reimbursed.

Norway: There is one private clinic whose expenses are not reimbursed.

<u>Portugal</u>: Only if performed in the public hospitals; no reimbursement in the private sector.

Slovakia: Partially.

<u>Slovenia</u>: Up to four cycles are reimbursed for the first and same for the second childbirth.

<u>Sweden</u>: The number of treatments that are financed by the social security system differs between the county councils.

United Kingdom: Treatment is free in National Health Service clinics, but is not very commonly used.

<u>United States</u>: Rhode Island law requires that health insurance provide coverage for medically necessary expenses incurred for diagnosis and treatment of infertility.

46. Is it lawful, for the purposes of practising M-A.P, to remove the following from a corpse:

a) sperm? (y/n) b) ova? (y/n)

- 47. Do you know if such an operation already been carried out? (y/n)
- 48. If so, were embryos formed from these gametes? (y/n)

Country	46 a	b	47	48	Country	46 a	b	47	48
Austria	n	n	/	/	Netherlands	nr	nr	n	ns
Belgium	ns	ns	ns	ns	Norway	nr	nr	n	/
Bulgaria	n	n	/	/	Poland	ns	ns	ns	ns
Cyprus	nr	/	/	/	Portugal	n	n	/	/
Czech Rep.	ns	ns	n	ns	Romania	nr	nr	ns	ns
Denmark	n*	n	n	/	Russia	ns	ns	ns	ns
Estonia	n	n	n	/	San Marino	nr	nr	ns	ns
Finland	ns	ns	n	/	Slovakia	n	n	n	/
France	n*	n*	n*	/	Slovenia	n	n	n	n*
Germany	n	n	n	/	Spain	nr	nr	n	/
Greece	ns*	ns*	ns	ns	Sweden	n	n	n	/
Hungary	y*	у*	n	/	Switzerland	n	n	ns	ns
Iceland	n	n	n	/	Turkey	n	n	ns	ns
Ireland	*	*	n	/	Ukraine	nr	nr	ns	ns
Italy	n*	n*	/	/	United Kingdom	у*	у	n	/
Latvia	nr	nr	no	/	Australia	n*	n	n	/
Liechtenstein	nr	nr	ns	ns	Canada	nr*	nr*	n	/
Lithuania	nr	nr	n	/	New Zealand	nr	nr	n	/
Luxembourg	nr	nr	ns	ns	United States	у	ns	у	у
Malta	n	n	/	/					

Denmark: This question has not been contemplated.

<u>France</u>: It is unlawful to remove gametes from a corpse both under the general rules for the use of medically-assisted procreation (access is restricted to couples in which both individuals are alive) and under the specific conditions relating to the donation of gametes.

Greece: In principle this is not allowed because it would constitute an insult to the dead person.

<u>Hungary</u>: In principle, the statutory provisions on organ and tissue transplantation apply to gametes, which may accordingly be removed where the deceased person has not objected before death.

Ireland: The legislation is ambiguous where deceased persons are concerned.

Italy : Article 4 (2) of the bill prohibits this explicitly.

Slovenia: This has almost certainly never happened in Slovenia.

<u>United Kingdom</u>: In principle, where all the appropriate consents have been obtained from the person while alive.

<u>Australia</u>: The Code of Practice that accompanies the Human Reproductive Technology Act (1991) of Western Australia prohibits this practice. On the other hand, the New South Wales Law Reform Commission published a Discussion Paper in 1988 that recommended that no regulation or prohibition of IVF be imposed upon the use of IVF procedures to achieve pregnancy with the stored gametes of a deceased person.

<u>Canada</u>: House of Commons Bill C-47 would prohibit removal of ova or sperm from a cadaver with the intention of fertilisation or implantation.
- 49. Is it lawful, for the purposes of practising M-A.P, to remove ovaries from a corpse? (y/n)
- 50. If so, who is required to give their consent:
 - a) the woman? (y/n)
 - b) the parents in the event of removal from an aborted foetus? (y/n)
 - c) an other person? (y/n)

Country	49	50 a	b	с	Country	49	50 a	b	с
Austria	n	/	/	/	Netherlands	nr	nr	nr	nr
Belgium	ns	ns	ns	ns	Norway	nr	nr	nr	nr
Bulgaria	n	/	/	/	Poland	ns	ns	ns	ns
Cyprus	nr	nr	nr	nr	Portugal	n	/	/	/
Czech Rep.	ns	ns	ns	ns	Romania	nr	nr	nr	nr
Denmark	n	ns	ns	ns	Russia	ns	ns	ns	ns
Estonia	n	/	/	/	San Marino	nr	nr	nr	nr
Finland	ns	ns	ns	ns	Slovakia	n	/	/	/
France	n	/	/	/	Slovenia	n	/	/	/
Germany	n*	/	/	/	Spain	nr	/	/	/
Greece	ns*	ns	ns	ns	Sweden	n	/	/	/
Hungary	ns*	ns	ns	ns	Switzerland	n	/	/	/
Iceland	n	/	/	/	Turkey	n	/	/	/
Ireland	ns	ns	ns	ns	Ukraine	nr	nr	nr	nr
Italy	n	/	/	/	United Kingdom	y*	у	n**	y***
Latvia	nr	nr	nr	nr	Australia	ns	/	/	/
Liechtenstein	nr	nr	nr	nr	Canada	nr*	/	/	/
Lithuania	nr	nr	nr	nr	New Zealand	ns	/	/	/
Luxembourg	nr	nr	nr	nr	United States	ns	/	/	/
Malta	n	/	/	/					

Germany: Ovum donation is prohibited by the Protection of the Human Embryo Act.

Greece: In principle this is not allowed because it would constitute an insult of the dead person.

<u>Hungary</u>: The statutory provisions on organ and tissue transplantation are applicable in principle to such removal.

<u>United Kingdom</u>: * In principle, where the appropriate consent has been obtained from the person while alive.

** Removal from an aborted foetus is unlawful.

*** The person who has charge of the body must authorise removal.

<u>Canada</u>: House of Commons Bill C-47 would prohibit removal of ova or sperm from a cadaver with the intention of fertilisation or implantation.

51. Is the possibility of depositing one's gametes for possible personal use in the future:

a) available to anyone, including a single person, who is at risk (of infertility or another hazard)? (y/n)

b) available only to couples provided that one member is at risk (of infertility or another hazard)? (y/n)

c) available to all couples, with no conditions attached? (y/n)

d) freely available to anyone? (y/n)

Country	a	b	c	d	Country	a	b	c	d
Austria	n	n	n	n	Netherlands	у	n	n	n
Belgium	n	n	у	n	Norway	n	у	n	n
Bulgaria	ns	ns	ns	ns	Poland	ns	ns	ns	ns
Cyprus		у			Portugal	nr	nr	nr	nr
Czech Rep.	ns	ns	ns	ns	Romania	nr	nr	nr	nr
Denmark	у	n	у	n*	Russia	ns	ns	ns	ns
Estonia	у	n	у	у	San Marino	nr	nr	nr	nr
Finland	у	n	n	n	Slovakia	n	n	ns	n
France	nr*	nr	n	n	Slovenia	у	n	n	n
Germany	у	n	у	у	Spain	у	/	/	/
Greece	nr	nr	nr	nr	Sweden	у	n	n	n
Hungary	ns	ns	ns	ns	Switzerland	у	n	у	у
Iceland	у	n	у	y*	Turkey	nr	nr	nr	nr
Ireland	n	у	n	n	Ukraine	nr	nr	nr	nr
Italy	ns	ns	ns	ns	United Kingdom	у	n	у	у
Latvia	n	n	n	n	Australia	у	n	у	у
Liechtenstein	nr	nr	nr	nr	Canada	ns	ns	ns	ns
Lithuania	nr	nr	nr	nr	New Zealand	ns	/	/	/
Luxembourg	nr	nr	nr	nr	United States	у	n	у	у
Malta	n	n	n	n					

<u>Denmark</u>: At present, unfertilised ova cannot be stored. In exceptional circumstances, sperm may be frozen.

<u>France</u>: Bioethics legislation has made medically-assisted procreation available to couples whose infertility is medically certified as being pathological in nature. However, it may be considered that if a single person is likely to fulfil these two conditions in the future, particularly in view of the pathology from which he or she suffers and the treatments he or she must undergo, then depositing and freezing gametes is not incompatible with the law, since they would only constitute the first stage in any future act of medically-assisted procreation.

<u>Iceland</u>: Gametes can only be stored if the purpose is own personal use in future, donation for research or donation in connection with medically-assisted procreation. The donor shall give a written consent for the storage in accordance with the storage's purpose following information on the effect of the storage on the gametes and the general conditions of storage of gametes.

52. a) must the person depositing his or her gametes be at risk of infertility? (y/n) b) can that person be at risk of another hazard? (y/n)

Country	а	b	Country	a	b
Country	a		Country	a	0
Austria	/	/	Netherlands	yes	no
Belgium	ns	ns	Norway	yes	no
Bulgaria	ns	ns	Poland	ns	ns
Cyprus	yes	no	Portugal	nr	nr
Czech Rep.	ns	ns	Romania	nr	nr
Denmark	yes	yes*	Russia	ns	ns
Estonia	no	no	San Marino	nr	nr
Finland	ns	ns	Slovakia	/	/
France	nr	nr	Slovenia	no	yes*
Germany	no	yes	Spain	yes	yes
Greece	nr	nr	Sweden	yes	no
Hungary	ns	ns	Switzerland	no	yes
Iceland	ns	ns	Turkey	nr	nr
Ireland	yes	no	Ukraine	nr	nr
Italy	nr	ns	United Kingdom	no	yes*
Latvia	/	/	Australia	ns	ns
Liechtenstein	nr	nr	Canada	/	/
Lithuania	nr	nr	New Zealand	/	/
Luxembourg	nr	nr	United States	no	no
Malta	nr	nr			

<u>Denmark</u>: For instance, persons requiring radiation treatment of their "gonads".

<u>Slovenia</u>: Medical treatment with risk of damage to the genome of the germline cells, e.g. radiation or chemotherapy for cancer, or any other risk of relevance.

<u>United Kingdom</u>: Any risk of relevance.

- 53. If a person who has made a deposit for personal use dies, can the gametes be used:
 - a) for another couple, provided that the deceased has given his or her prior authorisation? (y/n)
 - b) for another couple, without the deceased person's authorisation? (y/n)
 - c) for other purposes (such as research)? (y/n)

Country	а	b	с	Country	a	b	с
Austria	no	no	no	Netherlands	nr	nr	nr
Belgium	no	no	no	Norway	no	no	no
Bulgaria	ns	ns	ns	Poland	ns	ns	ns
Cyprus	ns	ns	ns	Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	ns	ns	ns	Russia	ns	ns	ns
Estonia	yes	no	yes	San Marino	nr	nr	nr
Finland	ns	no	ns	Slovakia	no	no	no
France	no*	no*	nr	Slovenia	no	no	yes*
Germany	no	no	yes	Spain	yes	yes*	yes*
Greece	nr	nr	nr	Sweden	no	no	no
Hungary	ns	ns	ns	Switzerland	ns	ns	ns
Iceland	yes	no	yes	Turkey	no*	ns	ns
Ireland	no	no	no	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	yes	no	yes*
Latvia	nr	nr	nr	Australia	no*	no	ns*
Liechtenstein	nr	nr	nr	Canada	ns	ns	ns
Lithuania	/	/	/	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes	no	ns*
Malta	nr	nr	nr				

- 80 -

<u>France</u>: The donation of gametes and their storage for personal use are two entirely separate operations. No provision allows gametes which have been stored for personal use to be used for donation.

<u>Slovenia</u>: With prior authorization by the donor and subject to the approval by research committee. However, sperm donation has become extremely rare in Slovenia, limited to strict medical criteria (frequency estimated at one or two in about 2000 cycles performed in a year).

<u>Spain</u>: The law states that after two years of cryogenic preservation, gametes or pre-embryos that are not from donors are made available to the storage banks.

<u>Turkey</u>: There are no donations.

United Kingdom: If prior permission has been obtained.

<u>Australia</u>: This is not explicitly prohibited, although the Code of Practice that accompanies the Human Reproductive Technology Act (1991) of Western Australia prohibits the use of sperm in an artificial fertilization procedure after the death of the gamete provider.

<u>United States</u>: This is not explicitly prohibited.

- 54. Does legislation stipulate a maximum time period for storing gametes? (y/n)
- [55. If so, how long is this period?]

Country	Rep.	Country	Rep.
Austria	yes*	Netherlands	no
Belgium	nr	Norway	yes
Bulgaria	ns	Poland	ns
Cyprus	ns	Portugal	nr
Czech Rep.	yes*	Romania	nr
Denmark	yes*	Russia	ns
Estonia	no	San Marino	nr
Finland	no	Slovakia	no
France	no	Slovenia	yes*
Germany	no	Spain	yes*
Greece	no	Sweden	yes*
Hungary	ns	Switzerland	yes*
Iceland	yes*	Turkey	ns
Ireland	ns	Ukraine	nr
Italy	ns	United Kingdom	yes*
Latvia	nr	Australia	yes*
Liechtenstein	nr	Canada	ns*
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	no
Malta	no		

<u>Austria</u>: The period is one year.

Czech Republic: There is no legislation on this subject - however the draft code on ethics deals with it.

<u>Denmark</u>: Ova may be stored for up to two years, at the expiry of which period the ova shall be destroyed. There is no time period for storing sperm.

Iceland: The maximum storage period is 10 years.

<u>Slovenia</u>: Gametes may not be stored beyond 6 years with a possible extension for justifiable reasons such as medical treatment with risk of damage to the genome of the germ line cells, when a request for MAP is likely to be made in later life.

<u>Spain</u>: Sperm may be cryogenically preserved in approved gamete banks for a maximum of five years. Cryogenic preservation of ova for the purposes of medically assisted procreation is prohibited.

Sweden: The period is one year but may be extended.

<u>Switzerland</u>: A person's gametes are stored, with his/her written consent, for 5 years. A longer period is authorised for persons who need to undergo treatment possibly causing sterility. Consent to store gametes may be withdrawn in writing at any time. In that case, the gametes must be destroyed forthwith.

<u>United Kingdom</u>: The maximum storage period is 10 years but regulations made under the HFE Act 1990 permit longer storage in precisely defined circumstances.

<u>Australia</u>: South Australia prohibits storage of embryos longer than 10 years. In Victoria, there are no statutory time limits for storage. In Western Australia, ova which are being fertilised or embryos must not be stored for more than three years.

<u>Canada</u>: The current recommendations for storage is ten years for gametes and five years for embryos with different conditions imposed.

56. Is there a maximum number of ova that may be fertilised at any one time to ensure the success of the procreation:

a) at the first attempt? (y/n)b) at subsequent attempts? (y/n)

Country	а	b	Country	а	
Austria	ns	ns*	Netherlands	ns	ns
Belgium	nr	nr	Norway	no	no
Bulgaria	ns	ns	Poland	ns	ns
Cyprus	ns	ns	Portugal	nr	nr
Czech Rep.	ns	ns	Romania	nr	nr
Denmark	no	no	Russia	ns	ns
Estonia	no	no	San Marino	nr	nr
Finland	no	no	Slovakia	yes	ye
France	nr*	ns	Slovenia	no	no
Germany	yes	yes	Spain	no	no
Greece	nr	nr	Sweden	no	no
Hungary	ns	ns	Switzerland	ns	ns
Iceland	no	no	Turkey	ns	ns
Ireland	no	no	Ukraine	nr	nr
Italy	ns	ns	United Kingdom	no	no
Latvia	nr	nr	Australia	no	no
Liechtenstein	nr	nr	Canada	nr	nr
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	no	no
Malta	nr	nr			

<u>Austria</u>: Austrian legislation does not set a maximum number. However it limits the number of ova that may be fertilised to a number necessary to ensure a success of the procreation within a cycle according to the state of the art.

<u>France</u>: French legislation does not set a maximum number. However it does stipulate that both members of the couple must record in writing their decision as to the number of ovocytes it will be attempted to fertilise (Article L.152-3 of the Public Health Code).

57. Is it lawful to store : 6

- a) fertilised ova after syngamy? (y/n)
- b) fertilised ova before syngamy? (y/n)
- c) fertilised ova, without distinction? (y/n)

Country	a	b	с	Country	а	b	с
Austria	yes	yes	yes	Netherlands	ns	ns	ns*
Belgium	nr	nr	nr	Norway	ns	ns	ns
Bulgaria	ns	ns	ns	Poland	ns	ns	ns
Cyprus	ns	ns	ns	Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	nr	nr	yes	Russia	ns	ns	ns
Estonia	nr	nr	yes	San Marino	nr	nr	nr
Finland	nr	nr	yes	Slovakia	no	no	no
France	nr	nr	yes	Slovenia	nr	nr	yes
Germany	no*	yes	no	Spain	yes	yes	no
Greece	nr	nr	nr	Sweden	nr	nr	yes
Hungary	ns	ns	ns	Switzerland	nr	nr	yes
Iceland	yes	yes	yes	Turkey	nr	nr	nr
Ireland	no	no	no	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	nr	nr	yes
Latvia	nr	nr	nr	Australia	nr	nr	yes*
Liechtenstein	nr	nr	nr	Canada	nr	nr	nr
Lithuania	/	/	/	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	nr	nr	yes
Malta	no	no	no				

⁶ For the attention of the consultants :

Distinction between fertilised ova before and after syngamy exists in particular in German law. In most other countries, answer may be given only to c).

Germany: Only so-called spare embryos may be stored.

Netherlands: Only sound embryos at the 8 cell stage which have not been implanted are stored.

<u>Australia</u>: In Western Australia, ova which are being fertilised must not be stored unless the primary intention of the storage is their "probable future implantation."

58. Is there a maximum number of embryos that may be implanted at any one time to ensure the success of the procreation:

a) at the first attempt? (y/n)b) at subsequent attempts? (y/n)

Country	а	b	Country	a	b
Austria	ns	ns	Netherlands	yes*	ns
Belgium	nr*	ns	Norway	nr*	nr
Bulgaria	ns	ns	Poland	ns	ns
Cyprus	ns	ns	Portugal	nr	nr
Czech Rep.	yes*	yes	Romania	nr	nr
Denmark	yes*	yes	Russia	ns	ns
Estonia	no	no	San Marino	nr	nr
Finland	no	no	Slovakia	no	no
France	yes	yes	Slovenia	yes*	yes*
Germany	yes	yes	Spain	no	no
Greece	nr	nr	Sweden	nr*	nr
Hungary	yes*	yes	Switzerland	yes*	ns
Iceland	no	no	Turkey	yes*	yes*
Ireland	yes*	yes	Ukraine	nr	nr
Italy	ns	ns	United Kingdom	yes*	yes*
Latvia	nr	nr	Australia	ns	ns
Liechtenstein	nr	nr	Canada	nr	nr
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	ns	ns
Malta	nr	nr			

- 88 -

Belgium: In average, 3 embryos are implanted per cycle.

<u>Czech Republic</u>: Implantation of more than 3 embryos at one time is permissible for medical reasons. Furthermore, selective reduction of a multiple pregnancy is not regarded as abortion because the operation is intended to maintain the pregnancy under optimum conditions for the mother and child.

Denmark: Maximum 3 according to the National Health Council directive.

Hungary: A maximum of 3 embryos.

Ireland: In principle 3, but no maximum is stipulated.

Netherlands: In practice, 2-3 embryos.

<u>Norway</u>: Not specified. Hospitals confine themselves to two or three embryos voluntarily and by common agreement.

Slovenia: Two or maximal three embryos may be implanted at each attempt.

Sweden: Unregulated, but the practice is to implant 2 or 3 embryos.

<u>Switzerland</u>: The draft law on medically-assisted procreation restricts the number of embryos transferred per cycle to three.

Turkey: 2-4 embryos are implanted at the first attempt and 3-4 at the second attempt.

United Kingdom: 3 embryos maximum.

- 59. Does legislation stipulate a maximum time period for storing embryos? (y/n)
- [60. If so, how long is this period? (y/n)]
- 61. Once this period has expired, what happens to the embryos:
 - a) are they destroyed? (y/n)
 - b) may they be donated to another couple? (y/n)
 - c) may they be used for research? (y/n)

Country	59	61a	b	с	Country	59	61a	b	с
Austria	у	у	n	n	Netherlands	n	/	/	/
Belgium	nr	nr	nr	nr	Norway	у*	у	n	n
Bulgaria	ns	ns	ns	ns	Poland	nr	nr	nr	nr
Cyprus	ns	ns	ns	ns	Portugal	nr	nr	nr	nr
Czech Rep.	nr*	ns	ns	ns	Romania	nr	nr	nr	nr
Denmark	у*	у	n	n	Russia	ns	ns	ns	ns
Estonia	у*	у	n	у	San Marino	nr	nr	nr	nr
Finland	n	/	/	/	Slovakia	no	/	/	/
France	у*	у*	у	n	Slovenia	у*	у	n	y**
Germany	n	/	/	/	Spain	у*	nr	nr	nr
Greece	n	/	/	/	Sweden	у*	у	n	n**
Hungary	ns	ns	ns	ns	Switzerland	у*	ns	ns	ns
Iceland	у*	у	ns	n	Turkey	у*	у	ns	ns
Ireland	n*	n**	n	n	Ukraine	nr	nr	nr	nr
Italy	ns	ns	ns	ns	United Kingdom	у*	**	**	**
Latvia	nr	nr	nr	nr	Australia	у	у	у	n
Liechtenstein	nr	nr	nr	nr	Canada	nr*	/	/	/
Lithuania	nr	nr	nr	nr	New Zealand	nr	/	/	/
Luxembourg	nr	nr	nr	nr	United States	ns*	/	/	/
Malta	n*	/	/	/					

<u>Czech Republic</u>: The draft ethical code provides for cryopreservation of embryos for one year. This may be extended on medical grounds.

Denmark: The maximum storage time is two years.

Estonia: According to the draft law, the maximum storage period is 3 years.

<u>France</u>: The French law of 29 July 1994 states that embryos no longer need to be stored if they existed prior to promulgation of the law, are no longer required by the parents, have been in storage for five years or more, and cannot be implanted.

<u>Iceland</u>: The maximum storage period is 5 years. Embryos can only be stored in order to use it again in the woman providing the ovum or in the wife/partner of the man providing the sperm. Storage of embryos for other purposes is prohibited. The condition of the storage is that the man or the woman providing the gametes give a written consent for the storage in accordance with the purpose of the storage following information on the effect of the storage on the embryo and the general conditions of storage of the embryo.

<u>Ireland</u>: * Storage is implicitly brief but no maximum is stipulated. ** According to Medical Council guidelines, all embryos are to be implanted.

Malta: No provision is made to allow storage of embryos.

Norway: The maximum storage period is 3 years.

<u>Slovenia</u>: * The maximum storage period is 6 years. ** This is subject to approval by the National Medical Ethics Committee.

Spain: The maximum storage period is 5 years.

<u>Sweden</u>: * The maximum storage period is one year. ** The eggs may be donated for research before the period has expired.

<u>Switzerland</u>: Storage of embryos is allowed only in exceptional cases for subsequent transfer because only fertilised ova needed to induce a pregnancy during one cycle can be developed outside the woman's body.

<u>Turkey</u> : The maximum storage period is 3 years. In case of common request of spouses or death of one of the spouses or divorce the frozen embryos are destroyed without delay. In vitro and Embryo Transfer Centers have the duty to inform the Ministry of Health on preservation, use and destruction of embryos within the periods to be fixed by the scientific Board for methods on treatment for assisting reproduction. In carrying out preservation, use and destruction of embryos, the form for preservation and the form for destruction of embryos are filled out together with the periods for methods for medically assisted reproduction.

<u>United Kingdom</u>: * The maximum storage period is 5 years but regulations made under the HFE Act 1990 permit longer storage in precisely defined circumstances.

** After this period, they may be used for research, donated to another couple, or allowed to perish according to the consent given by both of the persons whose gametes went into creating the embryo.

<u>Canada</u>: The current recommendation for storage is ten years for gametes and five years for embryos.

<u>United States</u>: A few States ban the frozen embryo process completely: Minnesota, Michigan and Illinois.

- 62. Does legislation stipulate what happens to surplus embryos? (y/n)
- 63. If not, who decides what happens to surplus embryos:

a) the couple? (y/n)b) the medical team? (y/n)

Country	62	63a	b	Country	62	63a	b
Austria	yes*	/	/	Netherlands	no*	yes	no
Belgium	nr	nr	nr	Norway	no	no	yes
Bulgaria	ns	ns	ns	Poland	nr	ns	ns
Cyprus	nr	nr	nr	Portugal	no	ns	ns
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	yes	/	/	Russia	ns	ns	ns
Estonia	yes*	/	/	San Marino	nr	nr	nr
Finland	no	ns	ns	Slovakia	no	no	yes
France	yes*	yes*	no	Slovenia	yes	yes*	/
Germany	no	ns	ns	Spain	yes	/	/
Greece	no	yes	ns	Sweden	yes	/	/
Hungary	*	yes	no	Switzerland	ns	ns	ns
Iceland	no	yes	yes	Turkey	yes*	/	/
Ireland	yes	/	/	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	no	yes	no
Latvia	nr	nr	nr	Australia	yes	/	/
Liechtenstein	nr	nr	nr	Canada	nr	/	/
Lithuania	nr	nr	nr	New Zealand	nr	/	/
Luxembourg	nr	nr	nr	United States	no	yes*	no
Malta	nr	nr	nr				

Austria: See answer to previous question.

Estonia: According to the draft law, the surplus embryos are used for scientific research but the consent of the couple is necessary.

<u>France</u>: According to Article L. 152-3 of the Public Health Code, storage of surplus embryos is allowed for a maximum period of 5 years but each year, the couple shall be consulted as to wether they still wish to become parents.

See also answers to the two previous questions.

Hungary: According to the ethical code, it is for the couple to decide what is done with surplus embryos.

Netherlands: Legislation is prepared.

Slovenia: The consent of the couple is needed before embryos are used for research.

<u>Turkey</u>: Embryos can be frozen with the consent of both spouses.

<u>United States</u>: Case law has addressed this issue.

- 64. Are there conditions for donating:
 - a) sperm? (y/n)
 - b) ova? (y/n)
 - c) embryos (in this case, "anyone" refers to the woman or the couple)? (y/n)

Country	a	b	c	Country	a	b	c
Austria	yes	/*	/*	Netherlands	yes	yes	yes
Belgium	ns	ns	ns	Norway	no	*	*
Bulgaria	yes	yes	yes	Poland	ns	ns	ns
Cyprus	no	no	no	Portugal	nr	nr	nr
Czech Rep.	yes	yes	yes	Romania	nr	nr	nr
Denmark	yes	yes	*	Russia	ns	ns	ns
Estonia	yes	yes	yes	San Marino	nr	nr	nr
Finland	no	no	no	Slovakia	yes	yes	no
France	yes	yes	yes	Slovenia	yes	yes	*
Germany	no	/*	no*	Spain	yes	yes	yes
Greece	nr	nr	nr	Sweden	ns	ns	ns
Hungary	yes	no	no	Switzerland	yes*	ns	ns
Iceland	no	no	*	Turkey	nr*	nr	nr
Ireland	*	*	*	Ukraine	nr	nr	nr
Italy	ns*	ns	ns	United Kingdom	yes	yes	yes
Latvia	yes	yes	no	Australia	yes	yes	yes
Liechtenstein	nr	nr	nr	Canada	nr	nr	nr
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes	yes	yes
Malta	nr	nr	nr				

- 95 -

<u>Austria</u>: The donation of ova or embryos is illegal: § 3(3) FMedG stipulates that viable cells may only be used upon the woman from whom they stem.

Denmark: Donation of embryos is prohibited.

Germany: Donations of ova and embryos are prohibited, excepted for so-called spare embryos.

Iceland: Donation of embryos is prohibited.

Ireland: The guidelines apply principally to couples.

<u>Italy</u>: There are two Health Ministry circulars of 1987 and 1992 laying down certain procedures for collection of sperm and transplantation of organs, tissues and bone marrow, with the aim of preventing transmission of the AIDS virus and other pathogens.

Norway: Donation of ova and embryos is prohibited.

Slovenia: Donation of embryos is prohibited.

<u>Switzerland</u>: Donation of ova and embryos is prohibited.

Turkey: There are no donations in Turkey.

65. If so, those conditions are:

a) the age? (y/n) b) the health? (y/n) c) other? (y/n)

Country	a	b	с	Country	a	b	c
Austria	no	yes	yes*	Netherlands	no	yes*	no
Belgium	ns	ns	ns	Norway	*	/	/
Bulgaria	yes	yes*	yes*	Poland	ns	ns	ns
Cyprus	nr	nr	nr	Portugal	nr	nr	nr
Czech Rep.	yes*	yes*	yes*	Romania	nr	nr	nr
Denmark	yes*	**	yes*	Russia	ns	ns	ns
Estonia	yes	yes	no	San Marino	nr	nr	nr
Finland	/	/	/	Slovakia	yes*	yes*	yes*
France	no	yes	yes*	Slovenia	yes	yes	yes*
Germany	/	/	/	Spain	yes	yes	yes*
Greece	/	/*	/	Sweden	/	/	/
Hungary	no	yes*	no	Switzerland	no	yes*	yes
Iceland	/	/	/	Turkey	nr	nr	nr
Ireland	/	/	/	Ukraine	nr	nr	nr
Italy	ns	yes*	ns	United Kingdom	yes	yes	no
Latvia	ns	yes	ns	Australia	yes	yes	yes
Liechtenstein	nr	nr	nr	Canada	/	/	/
Lithuania	nr	nr	nr	New Zealand	/	/	/
Luxembourg	nr	nr	nr	United States	yes	yes	yes
Malta	nr	nr	nr				

<u>Austria</u>: In practice the hospital must satisfy itself that the sperm will make it possible to induce a pregnancy and that the health of the mother and child are not at risk.

<u>Bulgaria</u>: Donation is open to any Bulgarian national between 18 and 40 years of age. The donor must be in good physical and mental health and not suffer from a hereditary disease. Donors must undergo a health check in a sterility consultation centre and test negative for AIDS, syphilis and hepatitis B. There must be no blood relationship up to the 4th degree with the woman.

<u>Czech Republic</u>: A sperm donor may not be over 40 years of age. According to the ethical code, donation of ova should be subject to an age limit of 35 years.

A sperm donor must be in good health with no apparent genetic risks, and have no direct kinship with the woman receiving the sperm.

<u>Denmark</u>: * Donation of ova shall take place only where the ova are collected as part of an in vitro treatment of the donor woman. Since in vitro fertilisation shall be available only to woman who are not older than 45 years of age, donation of ova is limited to an age condition. ** Donors undergo thorough screening tests.

<u>France</u>: 1. Where the donation of gametes is concerned: without prejudice to the conditions which the recipient couple must fulfil, the following criteria apply:

- health criteria;
- the donor must form part of a couple who have procreated;
- the donor and the other member of the donor couple must both give their written consent.

2. Where embryo donation is concerned: without prejudice to the conditions which the recipient couple must fulfil, the following criteria apply:

- health criteria;
- both members of the donor couple must give their written consent, recorded in the presence of a judicial authority.

<u>Greece</u>: The risk of transmitting a hereditary or infectious disease and of any other factor posing a danger to the mother is investigated in practice.

Hungary: The donor must be in good health and there must be no hereditary disease in the family.

<u>Italy</u>: Two Health Ministry circulars of 1987 and 1992 have laid down certain conditions for the collection of sperm in order to prevent the transmission of HIV virus and other pathogens.

<u>Netherlands</u>: The donor must be in good health.

Norway: Almost all sperm for insemination is imported from Denmark.

<u>Slovakia</u>: The donor should be aged not more than 40, in good health, with no apparent genetic risks, and have no direct kindship with the woman receiving the sperm.

<u>Slovenia</u>: Repeated donations by the same donor may be made only to the same center. Donor's consent must be obtained to each use of the donated gametes. After donor's death, his gametes may not be used.

<u>Spain</u>: The donor must be over 18, in possession of full legal capacity, and meet certain physical and psychological requirements. Gametes are tested for HIV and for other pathogenic agents.

<u>Switzerland</u>: Sperm donors are carefully selected to avert any risk to the woman's health. A man can donate sperm to one centre only.

66. Is the number of children born from the gametes of any one donor limited? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	yes*
Belgium	nr	Norway	no
Bulgaria	yes*	Poland	ns
Cyprus	ns	Portugal	nr
Czech Rep.	ns	Romania	nr
Denmark	yes*	Russia	ns
Estonia	yes*	San Marino	nr
Finland	no	Slovakia	no
France	yes*	Slovenia	yes*
Germany	no	Spain	yes*
Greece	nr	Sweden	no*
Hungary	no	Switzerland	yes*
Iceland	ns	Turkey	nr
Ireland	/	Ukraine	nr
Italy	ns	United Kingdom	yes*
Latvia	nr	Australia	ns
Liechtenstein	nr	Canada	nr
Lithuania	yes	New Zealand	nr
Luxembourg	nr	United States	no
Malta	nr		

[67. If so, what is that limit?]

- 100 -

<u>Bulgaria</u>: A donor's genetic material acceptable only between the ages of 18 and 40 years, may be used for not more than 3 inseminations.

Denmark: For sperm donation only. Locally concentrated sperm donors under 30 are rejected.

Estonia: According to the draft law, no more than 6 children.

France: Use of the same donor's gametes may not deliberately lead to the birth of more than 5 children.

<u>Netherlands</u>: The number of children conceived with one donor's gametes is restricted to 10 or thereabouts.

Slovenia: Limited to two children.

Spain: The number of children born from the same donor's gametes may not exceed 6.

Sweden: The maximum number of children is not regulated by law, but a maximum of 6 is recommended.

Switzerland: The same donor's sperm can be used for procreating a maximum of 8 children.

<u>United Kingdom</u>: Limited to 10 children.

68. Is it lawful to use donations of the following for financial gain:

a) sperm? (y/n) b) ova? (y/n) c) embryos? (y/n)

Country	а	b	с	Country	a	b	с
Austria	no	/*	/*	Netherlands	no	no	no
Belgium	no	no	no	Norway	ns*	ns*	ns*
Bulgaria	nr*	nr	nr	Poland	no	no	no
Cyprus	nr	nr	nr	Portugal	no	no	no
Czech Rep.	no*	no*	no*	Romania	nr	nr	nr
Denmark	no	no	no	Russia	ns	ns	ns
Estonia	no	no	no	San Marino	nr	nr	nr
Finland	ns	ns	ns	Slovakia	yes*	no	no
France	no*	no*	no*	Slovenia	no	no	*
Germany	no*	no**	no**	Spain	no	no	no
Greece	ns	ns	ns	Sweden	no	no	no
Hungary	no	no	no	Switzerland	no*	ns	ns
Iceland	no	no	*	Turkey	nr	nr	nr
Ireland	no*	no*	no*	Ukraine	nr	nr	nr
Italy	no*	no*	no*	United Kingdom	no*	no*	no
Latvia	nr	nr	nr	Australia	no	no	no
Liechtenstein	nr	nr	nr	Canada	no*	no*	no*
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	no	no	no*
Malta	nr	nr	nr				

- 102 -

Austria: The donation of ova or embryos is illegal.

<u>Bulgaria</u>: The donor of genetic material is paid for each donation according to arrangements specified by the order. Should the genetic material not meet the requirements defined in the order, the donor would not be paid.

<u>Czech Republic</u>: The Order makes provision for enabling the donor to request remuneration (200-500 KC ie approximately 10/25 USD).

<u>France</u>: Anyone who procures gametes or embryos in return for any form of payment or acts as an intermediary in their procurement is liable to punishment.

<u>Germany</u>: * In respect of commercialisation, ie. going beyond reimbursement of costs. ** Ovum donation is prohibited. The same applies to embryo donation except for so-called spare embryos.

Iceland: Embryo donation is prohibited.

Ireland: Prohibition is implied.

Italy: The bill prohibits commercial exploitation of gametes, embryos and embryonic and foetal tissues.

Norway: This question is not relevant. Sperm is imported from Denmark, ova and embryo donation is prohibited.

<u>Slovakia</u>: The donor may request remuneration, to be paid with public funds.

Slovenia: Donation of embryos is prohibited by law.

<u>Switzerland</u>: Disposal or procurement for money of human genetic material is punishable under criminal law (Art. 30 (2) AP).

<u>United Kingdom</u>: Codes of practice provide for a small payment in consideration of the expense and inconvenience incurred.

<u>Canada</u>: House Bill C-47 would prohibit the commercial exchange of any ovum, sperm, zygote, embryo or foetus.

United States: Ovum donors are paid a standard amount of 2,500 dollars.

69.	Is the donor entitled to reimburs	ement of expenses	s incurred as a	result of the	donation? (y/n)
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Country	Rep.	Country	Rep
Country	Kep.	Country	Кср
Austria	yes*	Netherlands	yes
Belgium	nr	Norway	ns
Bulgaria	yes*	Poland	ns
Cyprus	nr	Portugal	nr
Czech Rep.	yes	Romania	nr
Denmark	no*	Russia	ns
Estonia	no	San Marino	nr
Finland	yes	Slovakia	yes
France	no	Slovenia	yes
Germany	nr	Spain	yes*
Greece	nr	Sweden	no
Hungary	yes	Switzerland	ns
Iceland	no	Turkey	nr
Ireland	no	Ukraine	nr
Italy	ns	United Kingdom	yes
Latvia	no	Australia	yes
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	yes
Malta	nr		

- 104 -

<u>Austria</u>: Under Article 16 FMEDG, remunerated sperm donation is prohibited but this does not preclude reimbursement of expenses incurred by the donor.

Bulgaria: Donors may be remunerated in accordance with the rules laid down by the Order.

Denmark: Donors nevertheless usually receive an allowance.

Spain: The donor is paid expenses incurred as a result of the donation.

70. May the donor:

a) stipulate conditions as to the destination of the donation (eg: the gametes may not be used in the same town or county)? (y/n)

b) choose who shall receive the donation? (y/n)

c) subsequently withdraw the donation (eg : if his or her marital status changes)? (y/n)

Country	a	b	с	Country	a	b	с
Austria	yes	yes	yes	Netherlands	no	no	yes*
Belgium	nr	nr	nr	Norway	ns	ns	ns
Bulgaria	no	no	no	Poland	ns	ns	ns
Cyprus	ns	ns	ns	Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	no	no	no	Russia	ns	ns	ns
Estonia	no	no	no	San Marino	nr	nr	nr
Finland	ns	ns	ns	Slovakia	no	no	no
France	no	no	no	Slovenia	no	no	yes
Germany	nr	nr	nr	Spain	no	no	no*
Greece	nr	nr	nr	Sweden	no	no	no
Hungary	ns	no	ns	Switzerland	yes*	ns	yes
Iceland	no	no	yes	Turkey	nr	nr	nr
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	ns	no	ns	United Kingdom	yes	no*	yes
Latvia	nr	nr	nr	Australia	yes*	yes*	yes**
Liechtenstein	nr	nr	nr	Canada	nr	nr	nr
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes	yes	yes
Malta	nr	nr	nr				

- 106 -

Netherlands: Particularly if the donor's marital status changes.

Spain: Donors may not withdraw the donation except where they need their gametes because of sterility.

<u>Switzerland</u>: Sperm may be used solely for the purposes to which the donor has agreed in writing (Art. 18 AP). This agreement may be subject to conditions, the nature of which is not specified.

United Kingdom: Except for donations of ova or sperm intended for relatives.

<u>Australia</u>:* Western Australia permits this. ** Victoria permits this.

- 71. In the case of in vitro fertilisation, is ovum donation:
 - a) allowed in general? (y/n)
 - b) allowed only in exceptional cases? (y/n)
- 72. If ovum donation is allowed only in exceptional cases, are those cases clearly defined? (y/n)

Country	71a	71b	72	Country	71a	71b	72
Austria	no	no	/	Netherlands	yes*	no	ns
Belgium	ns	nr	nr	Norway	no	ns	ns
Bulgaria	ns	ns	ns	Poland	ns	ns	ns
Cyprus	ns	ns	ns	Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	no	yes*	yes*	Russia	ns	ns	ns
Estonia	yes	no	/	San Marino	nr	nr	nr
Finland	yes	/	/	Slovakia	no	no	no
France	yes	no	/	Slovenia	no	yes	no*
Germany	no	no	/	Spain	yes	no	/
Greece	nr	nr	nr	Sweden	no	no	/
Hungary	ns	ns	ns	Switzerland	no	no	ns
Iceland	yes	/	/	Turkey	nr	nr	nr
Ireland	no	no	/	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	yes	no	/
Latvia	nr	nr	nr	Australia	yes	no	/
Liechtenstein	nr	nr	nr	Canada	nr	nr	/
Lithuania	nr	nr	nr	New Zealand	nr	nr	/
Luxembourg	nr	nr	nr	United States	yes*	no	/
Malta	nr	nr	nr				

Denmark: A woman making a donation must herself be subjected to in vitro fertilisation.

Netherlands: It happens rarely.

<u>Slovenia</u>: These hypothesises are determined according to the judgment of the medical team and subject to approval by the Advisory Committee for MAP.

<u>United States</u>: Only five states (North Dakota, Oklahoma, Texas, Florida and Virginia) have laws on ovum donation.
- 109 -

- 73. In the case of in vitro fertilisation, is embryo donation:
 - a) allowed in general? (y/n)b) allowed only in exceptional cases? (y/n)
- 74. If embryo donation is allowed only in exceptional cases, are those cases clearly defined? (y/n)
- [75. If so, please give details.]

Country	73a	b	74	Country	73a	b	74
Austria	no	no	/	Netherlands	yes*	no	ns
Belgium	nr	nr	nr	Norway	no	ns	ns
Bulgaria	ns	ns	ns	Poland	ns	ns	ns
Cyprus	nr	nr	nr	Portugal	nr	nr	nr
Czech Rep.	ns	ns	ns	Romania	nr	nr	nr
Denmark	no	no	/	Russia	ns	ns	ns
Estonia	yes	no	/	San Marino	nr	nr	nr
Finland	yes	no	/	Slovakia	no	no	no
France	no	yes	yes	Slovenia	no	no	/
Germany	no	yes	no*	Spain	yes	no	/
Greece	nr	nr	nr	Sweden	no	no	/
Hungary	ns	ns	ns	Switzerland	no	no	
Iceland	no	no	/	Turkey	nr	nr	nr
Ireland	no	no	/	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	yes	no	/
Latvia	nr	nr	nr	Australia	yes	no	/
Liechtenstein	nr	nr	nr	Canada	nr	nr	/
Lithuania	nr	nr	/	New Zealand	nr	nr	/
Luxembourg	nr	nr	nr	United States	yes	no	/
Malta	nr	nr	nr				

<u>Germany</u>: Only so-called spare embryos may be donated.

<u>Netherlands</u>: Not ruled by legislation as yet.

- 111 -

- 76. Generally speaking, who is considered in law as the mother of the child:
 - a) the woman carrying the child? (y/n)
 - b) the woman who produced the fertilised ovum? (y/n)
- 77. If it is the woman carrying the child, can the woman who donated the ovum be considered as the mother of the child in exceptional cases? (y/n)

Country	76a	b	77	Country	76a	b	77
Austria	yes	no	no	Netherlands	yes	no	no
Belgium	nr	nr	nr	Norway	yes*	no*	no*
Bulgaria	yes	no	no	Poland	yes	no	no
Cyprus	yes	no	ns	Portugal	yes	no	no
Czech Rep.	yes	no	no	Romania	nr	nr	nr
Denmark	yes	no	no*	Russia	ns	ns	ns
Estonia	yes	no	no	San Marino	nr	nr	nr
Finland	yes	no	no	Slovakia	yes	no	no
France	yes	no	no	Slovenia	yes	no	no
Germany	nr*	nr*	nr**	Spain	yes*	no	no
Greece	yes	no	no	Sweden	yes*	*	no
Hungary	yes	no	no	Switzerland	yes*	no	no
Iceland	yes	no	no	Turkey	ns	ns	ns
Ireland	yes	ns	ns	Ukraine	nr	nr	nr
Italy	yes	no	no	United Kingdom	yes	no	no
Latvia	nr	nr	nr	Australia	yes	no	ns
Liechtenstein	nr	nr	nr	Canada	yes*	no	no*
Lithuania	nr	nr	/	New Zealand	ns	ns	/
Luxembourg	nr	nr	nr	United States	yes	no	yes
Malta	nr*	nr	nr				

- 112 -

Denmark: Since donation only can take place anonymously.

<u>Germany</u>: * According to the Government Bill for an Act to Reform the Law Relating to Parent and Child Matters - currently under discussion before Parliament - it is to be made clear that the mother of the child shall only be the woman giving birth to the child.

** The Government Bill for an Act to Reform the Law Relating to Parent and Child Matters does not provide for any exceptions.

Malta: As donation of gametes or embryos is not practised, the case has not arisen.

Norway: Relevant regulations are contained in the Act relating to Parent and Child Matters.

Spain: In principle, the general rules on parentage are applied in M-A.P cases. The maternity affiliation is define by the childbirth.

<u>Sweden</u>: Donation for purposes of in vitro fertilisation is prohibited. If a child thus conceived abroad is born in Sweden, the woman carrying the child is legally the mother.

Switzerland: Donation of ova is prohibited.

<u>Canada</u>: According to the Civil Code of Quebec, the birth mother is the legal mother. The code also states that "participation in the parental project of another person by way of a contribution of genetic material to medically assisted procreation does not allow the creation of any bond of filiation between the contributor and the child born of that procreation" [Civil Code of Quebec (1994) art. 538-542].

78. In the case of utilisation of a donor's sperm, is the husband's or partner's consent required for insemination? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	yes
Belgium	yes	Norway	yes
Bulgaria	yes	Poland	no
Cyprus	yes	Portugal	yes
Czech Rep.	yes	Romania	nr
Denmark	yes	Russia	ns
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	yes
France	yes	Slovenia	yes
Germany	no*	Spain	yes*
Greece	yes	Sweden	yes
Hungary	yes	Switzerland	yes
Iceland	yes	Turkey	nr
Ireland	yes	Ukraine	nr
Italy	yes	United Kingdom	no*
Latvia	yes	Australia	yes
Liechtenstein	nr	Canada	yes*
Lithuania	yes	New Zealand	ns
Luxembourg	nr	United States	yes
Malta	*		

- 114 -

<u>Germany</u>: Written consent is necessary only for heterologous in vitro fertilisation and for heterologous gamete intrafallopian transfer.

Malta: Donation of gametes is not practised.

Spain: Consent is required only in the case of the husband of a married woman.

<u>United Kingdom</u>: The legal position in respect of paternity of the unborn child will depend on whether or not there was consent by the husband, or in the case of an unmarried couple, whether they sought treatment together.

Canada: House Bill C-47 prohibits the use of donated sperm without the donor's consent.

79. How is this consent given:

- a) orally? (y/n)
- b) in writing? (y/n)
- c) in the presence of the medical team? (y/n)
- d) before a judicial body? (y/n)
- e) in the presence of the medical team and before a judicial body, in turn? (y/n)

Country	a	b	c	d	e	Country	a	b	c	d	e
Austria	n	у	n	у	n	Netherlands	n	у	n*	n	n
Belgium	n	у	ns	ns	ns	Norway	n	у	ns	ns	ns
Bulgaria	n	у	ns	ns	ns	Poland	n	у	у	ns	ns
Cyprus	n*	у	у	ns	ns	Portugal	ns	ns	ns	ns	ns
Czech Rep.	n	у	у	n	n	Romania	nr	nr	nr	nr	nr
Denmark	ns	у	n	n	n	Russia	ns	ns	ns	ns	ns
Estonia	n	у	у	n	n	San Marino	nr	nr	nr	nr	nr
Finland	у	n	n	n	n	Slovakia	ns	у	у	ns	ns
France	n	у	у	n	n	Slovenia	/	у	у	n	n
Germany	/	/	/	/	/	Spain	n	у	у	/	/
Greece	nr	nr	nr	nr	nr	Sweden	n	у	n	n	n
Hungary	n	у	у	n	n	Switzerland	n	у	ns	ns	ns
Iceland	n	у	у	ns	ns	Turkey	nr	nr	nr	nr	nr
Ireland	ns	ns	ns	ns	ns	Ukraine	nr	nr	nr	nr	nr
Italy	n	у	у	ns	ns	United Kingdom	у	у	у	n	n
Latvia	n	у	у	n	n	Australia	у	у	у	n	n
Liechtenstein	nr	nr	nr	nr	nr	Canada	ns	ns	ns	ns	ns
Lithuania	n	у	у	n	nr	New Zealand	ns	ns	ns	ns	ns
Luxembourg	nr	nr	nr	nr	nr	United States	у	у	у	n	n
Malta	nr	nr	nr	nr	nr						

<u>Cyprus</u>: In the absence of statutory provisions, medical practice requires use of the donor's sperm where the husband or partner has given written consent in the presence of the medical team.

<u>Netherlands</u>: It has to be "available" for the medical team.

- 80. Is a husband who has consented to M-A.P with donor considered the legitimate father of the child? (y/n)
- 81. If a husband who has consented to M-A.P is considered the father of the child, can he nevertheless disclaim paternity:

a) only if he can prove that the child was not born as a result of M-A.P? (y/n) b) in other cases? (y/n)

Country	80	81a	b	Country	80	81a	b
Austria	yes	yes	no	Netherlands	yes	yes	no
Belgium	yes	yes	no	Norway	yes	no	no
Bulgaria	yes	ns	ns	Poland	ns	ns	ns
Cyprus	yes*	yes	no	Portugal	yes	yes	no
Czech Rep.	yes	yes	no	Romania	nr	nr	nr
Denmark	yes	yes	no	Russia	ns	ns	ns
Estonia	yes	yes	no	San Marino	nr	nr	nr
Finland	yes*	no	yes*	Slovakia	yes	yes*	no
France	yes	no	yes*	Slovenia	yes	yes	no
Germany	yes*	yes**	yes	Spain	yes	yes	no
Greece	yes	yes	no	Sweden	yes	yes	ns
Hungary	yes	ns	ns	Switzerland	yes	yes	no
Iceland	yes	yes	no	Turkey	nr	nr	nr
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	yes*	no	yes	United Kingdom	yes	yes	no
Latvia	nr	nr	nr	Australia	yes	ns	ns
Liechtenstein	nr	nr	nr	Canada	ns	yes*	ns
Lithuania	yes	no	no	New Zealand	ns	ns	ns
Luxembourg	nr	nr*	nr	United States	yes	ns	ns
Malta	nr	nr	nr				

Cyprus: The exception has yet to be applied.

Finland: If he proves that he cannot be its biological father of the child.

France: Consent to medically-assisted procreation is considered devoid of effect:

- in the event of death, the filing of an application for divorce or judicial separation or the termination of conjugal living, occurring before the medically-assisted procreation is carried out;

- if the man or the woman withdraws his or her consent in writing to the doctor responsible for providing the assistance before the medically-assisted procreation is carried out.

<u>Germany</u>: * See Federal Court case law of 7 April 1983 (BGHZ 87, 169) and BGH of 3 May 1995 (BGHZ 129, 297).

** But not only in the case referred to.

Italy: It can be disclaimed even if the man has consented, under certain conditions.

<u>Luxembourg</u>: Under Article 312 of the Civil Code, the husband may not disclaim paternity of a child conceived by artificial insemination, whether from himself or from another, with his written consent.

<u>Slovakia</u>: The husband can disclaim paternity if he succeeds in proving that the mother became pregnant by some other means.

<u>Canada</u>: The husband may disavow the child if he did not give consent to medically assisted procreation or if he proves that the child was not born of such procreation [Civil Code of Quebec, (1994) art. 538-542)

- 82. Is a male partner who has consented to M-A.P with donor considered the legitimate father of the child:
 - a) by virtue of the act the consent? (y/n)b) by a voluntary act of recognition? (y/n)
- 83. If he is not willing to take parental responsibilities, is it possible to take legal proceedings against him? y/n

Country	82a	b	83	Country	82a	b	83
Austria	yes*	yes	yes	Netherlands	no	yes	*
Belgium	no	yes	yes	Norway	yes	no	no
Bulgaria	ns	ns	ns	Poland	*		
Cyprus	yes	no	ns	Portugal	nr	yes	yes
Czech Rep.	no	no	no	Romania	nr	nr	nr
Denmark	yes*	no	yes	Russia	ns	ns	ns
Estonia	no	no	yes	San Marino	nr	nr	nr
Finland	no	yes	*	Slovakia	yes*	yes	yes
France	no	yes	yes*	Slovenia	yes	no	yes
Germany	no	yes*	no**	Spain	yes	no	yes
Greece	nr	nr	nr	Sweden	yes	no	yes
Hungary	ns	ns	ns	Switzerland	no*	no**	no
Iceland	yes*	ns	yes	Turkey	nr	nr	nr
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	ns	ns	ns	United Kingdom	yes	no	yes
Latvia	nr	nr	nr	Australia	yes	ns	yes
Liechtenstein	nr	nr	nr	Canada	yes*	no	yes
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes	ns	yes
Malta	nr	nr	nr		_		

- 120 -

Austria: Consent constitutes a legal presumption of being father.

Denmark: Consent also constitutes a legal undertaking to accept parental responsibilities.

Finland: Not before the deed of recognition.

<u>France</u>: Paternity out of wedlock is declared by the court in respect of a person who, after consenting to M-A.P, does not acknowledge the child thereby conceived (action to establish natural paternity).

<u>Germany</u>:* Recognition by the partner is necessary only in the case of a couple not married. ** He can not be forced to recognise paternity. But maintenance claims can be brought against him.

Iceland: And also due to specific legal provisions to that effect.

<u>Netherlands</u>: A new provision yet to be enacted should enable the child's mother to take legal action against the partner if he refuses to accept parental responsibility.

Poland: M-A.P is available only to married couples.

Slovakia: Donor artificial insemination is only possible between married partners.

<u>Switzerland</u>: * M-A.P by donation of sperm is reserved to couples who are married (Article 3, paragraph 3 of the Bill).

** The action of recognition is allowed only if the partner is the biological father.

<u>Canada</u>: "A person, who after consenting to medically assisted procreation, does not acknowledge the child born of such procreation is responsible to the child and to the mother of the child" [Civil Code of Quebec, (1994) art. 540]

-	121	-
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- 84. In the case of donation, is the principle of the secrecy of procreation respected? (y/n)
- 85. In the case of donation, is the principle of the secrecy of the donor's identity respected? (y/n)
- 86. Do the Courts have the power to identify the donor? (y/n)

Country	84	85	86	Country	84	85	86
Austria	yes	no*	/	Netherlands	yes	yes	no
Belgium	yes	yes	yes	Norway	yes	yes	no
Bulgaria	yes	ns	ns	Poland	yes	yes	ns
Cyprus	yes	yes	yes	Portugal	nr	nr	nr
Czech Rep.	yes*	yes	no	Romania	nr	nr	nr
Denmark	yes	yes	no	Russia	yes	yes	ns*
Estonia	yes	yes	no	San Marino	nr	nr	nr
Finland	yes	yes	ns	Slovakia	yes*	yes*	yes
France	yes	yes	no	Slovenia	yes	yes	no
Germany	nr	nr*	nr*	Spain	yes	yes	yes
Greece	yes	yes	nr	Sweden	ns	no*	yes
Hungary	yes*	yes	ns	Switzerland	no	no*	ns
Iceland	yes*	yes	no	Turkey	yes	ns	ns
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	yes	yes	ns	United Kingdom	yes	yes	yes
Latvia	yes	yes	nr	Australia	yes	yes	no*
Liechtenstein	nr	nr	nr	Canada	yes	yes	yes
Lithuania	yes	yes	no	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes	yes*	yes
Malta	nr*	nr	nr				

<u>Austria</u>: The secrecy of the donor's identity is not respected in so far as the child is allowed access to information concerning him/her.

<u>Czech Republic</u>: The artificial insemination is entered in the woman's medical record without disclosure of the donor's name. This entry is subject to medical confidentiality. According to the ethical code, the donor's identity is kept secret only if he, or the recipients, do not agree to its disclosure.

<u>Germany</u>: In principle the child has the right to know who his parents are (See Constitutional Court's case law BVerfGE 79, 256, 269; 90, 263, 271).

<u>Hungary</u>: Secrecy of procreation is stipulated by Article 6 of the 1981 order.

<u>Iceland</u>: If the donor wishes to keep his identity a secret the staff of the health institution is obliged to respect that request. If the donor does not ask for secrecy on his identity the health institution shall keep information on him in a special file. Should a child result from the treatment with the gametes from this donor information on the couple and the child shall be kept in the same file. In these cases the child can, when it becomes 18, ask for access to this file and the name of the donor. Should the child request such information on the donor the institution is obliged to inform the donor of this as soon as possible.

Malta: Donation of gametes is not practised.

<u>Russia</u>: The mother may ask for information on the donor and his nationality.

<u>Slovakia</u>: The artificial insemination is entered in the woman's medical record without disclosure of the donor's name, which is subject to medical confidentiality.

<u>Sweden</u>: The child has the right to know the donor's name.

<u>Switzerland</u>: A person's access to data concerning his parentage is guaranteed (Article 24 novies, para. 2g of the Constitution). A child is entitled at all times to receive particulars of the donor, including identity details.

Australia: This is possible under certain circumstances.

<u>United States</u>: Both ovum and sperm donors are increasingly being asked to consent to donor identification.

87. Is access to the donor's identity possible in order to analyze a possible hereditary risk to the child? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	yes
Belgium	nr	Norway	no
Bulgaria	ns	Poland	ns
Cyprus	yes	Portugal	nr
Czech Rep.	yes	Romania	nr
Denmark	no	Russia	ns
Estonia	yes	San Marino	nr
Finland	ns	Slovakia	yes
France	no*	Slovenia	yes*
Germany	nr	Spain	yes
Greece	nr	Sweden	yes
Hungary	no	Switzerland	yes
Iceland	no	Turkey	ns
Ireland	ns	Ukraine	nr
Italy	ns	United Kingdom	no*
Latvia	yes	Australia	ns
Liechtenstein	nr	Canada	yes*
Lithuania	yes	New Zealand	nr
Luxembourg	nr	United States	ns
Malta	nr		

<u>France</u>: If necessary, a doctor is only allowed access to non-identifying medical information needed for treatment (Articles L. 152-5 and L. 673-6 of the Public Health Code).

<u>Slovenia</u>: Only for the purpose of (confidential) access to the relevant data of the donor. His/her identity may not be revealed to the recipient couple or to the child.

<u>United Kingdom</u>: The Human Fertilisation and Embryology Authority would be able to provide relevant information.

<u>Canada</u>: Where serious injury could be caused to the health of a person born of such procreation or any of his descendants if he were deprived of the information he requires, the court may allow such information to be transmitted confidentially to the medical authorities concerned.

88.	If the child is	given	information	n on the donor	, is the d	onor informed?	(y/n))

Country	Rep.	Country	Rep.
Austria	no	Netherlands	no*
Belgium	ns	Norway	no
Bulgaria	ns	Poland	ns
Cyprus	ns	Portugal	nr
Czech Rep.	*	Romania	nr
Denmark	/	Russia	ns
Estonia	no*	San Marino	nr
Finland	ns	Slovakia	yes
France	/	Slovenia	*
Germany	nr	Spain	ns
Greece	ns	Sweden	nr
Hungary	*	Switzerland	yes*
Iceland	yes*	Turkey	ns
Ireland	ns	Ukraine	nr
Italy	ns	United Kingdom	no
Latvia	nr	Australia	ns*
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	ns
Malta	nr		

- 126 -

Czech Republic: The child does not have access to information concerning his/her biological father.

Estonia: According to the draft law.

Hungary: A child may not obtain any information concerning the identity of his/her biological father.

<u>Iceland</u>: If the donor wishes to keep his identity a secret the staff of the health institution is obliged to respect that request. If the donor does not ask for secrecy on his identity the health institution shall keep information on him in a special file. Should a child result from the treatment with the gametes from this donor information on the couple and the child shall be kept in the same file. In these cases the child can, when it becomes 18, ask for access to this file and the name of the donor. Should the child request such information on the donor the institution is obliged to inform the donor of this as soon as possible.

Netherlands: Information on the child concerning the donor is not given yet.

Slovenia: The child may not be informed.

<u>Switzerland</u>: Information may be supplied to the child but the donor may nevertheless refuse to meet the child.

Australia: In Victoria, a child may receive non-identifying information about the gamete donor.

89. May a filial relationship be established between a child conceived by M-A.P and the donor of the sperm:

a) in general? (y/n)b) only in exceptional cases? (y/n)

Country	а	b	Country	a	b
Austria	no	no	Netherlands	no*	yes
Belgium	no	no	Norway	no	no
Bulgaria	no	ns	Poland	no	no
Cyprus	ns	ns	Portugal	nr	nr
Czech Rep.	no	no	Romania	nr	nr
Denmark	no	no*	Russia	ns	ns
Estonia	no	no	San Marino	nr	nr
Finland	no	no	Slovakia	yes	no
France	no	no	Slovenia	no	no
Germany	yes	/	Spain	no	no
Greece	no	no	Sweden	no	yes
Hungary	no	no	Switzerland	no	yes*
Iceland	no	no	Turkey	no	no
Ireland	ns	ns	Ukraine	nr	nr
Italy	no*	yes	United Kingdom	no	no
Latvia	nr	nr	Australia	no	yes
Liechtenstein	nr	nr	Canada	no	yes
Lithuania	nr	nr	New Zealand	ns	ns
Luxembourg	nr	nr	United States	no	yes
Malta	nr	nr			

<u>Denmark</u>: Since donation only can take place anonymously.

<u>Italy</u>: There is no objection in principle to the child's being acknowledged by the donor if the woman's husband has disclaimed paternity.

<u>Netherlands</u>: By way of an exception, if the mother and the donor agree, the donor can acknowledge the child.

<u>Switzerland</u>: Paternity action is allowed where the sperm donation has not been performed as stipulated by law (Article 23 para. 3 AP). However, the donor incurs no liability for an infringement committed by others, and is assured by law that his donation will have no effects under family law, with the notable exceptions of entitlement to maintenance and rights of inheritance.

Country	Rep.	Country	Rep.
Austria	no	Netherlands	no
Belgium	no	Norway	no
Bulgaria	ns	Poland	no
Cyprus	nr	Portugal	nr
Czech Rep.	no	Romania	nr
Denmark	no	Russia	ns
Estonia	no	San Marino	nr
Finland	no	Slovakia	no
France	no	Slovenia	no
Germany	yes*	Spain	no
Greece	nr	Sweden	no
Hungary	no	Switzerland	no
Iceland	no	Turkey	nr
Ireland	ns	Ukraine	nr
Italy	ns	United Kingdom	no
Latvia	nr	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	ns
Malta	nr		

90. May proceedings for maintenance be brought against the donor by the child? (y/n)

Germany: Only if paternity has been established.

91.	If the donor's identity is known, may he or she claim, in one way or another, allowances from the
	child? (y/n)

Country	Rep.	Country	Rep.
Austria	no	Netherlands	no
Belgium	nr	Norway	no
Bulgaria	ns	Poland	no
Cyprus	nr	Portugal	nr
Czech Rep.	no	Romania	nr
Denmark	no	Russia	ns
Estonia	no	San Marino	nr
Finland	no	Slovakia	ns
France	no	Slovenia	no
Germany	/*	Spain	no
Greece	nr	Sweden	no
Hungary	no	Switzerland	no
Iceland	no	Turkey	nr
Ireland	ns	Ukraine	nr
Italy	ns	United Kingdom	no
Latvia	nr	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	ns
Malta	nr		

<u>Germany</u>: Only if paternity of the sperm donor has been established could the donor have claims vis-à-vis the child like another father.

92. Even in the absence of filial relationship, does the child have the right to request, "at an appropriate age", information on:

a) his or her conception? (y/n)

b) the identity of the biological parents? (y/n)

Country	а	b	Country	а	
Austria	/	/	Netherlands	yes	no
Belgium	no	no	Norway	no	no
Bulgaria	ns	ns	Poland	nr	nr
Cyprus	no	no	Portugal	nr	nr
Czech Rep.	no	no	Romania	nr	nr
Denmark	no	no	Russia	ns	ns
Estonia	no	no	San Marino	nr	nr
Finland	no	no	Slovakia	yes	no
France	no	no	Slovenia	yes	no
Germany	nr*	nr*	Spain	yes	no
Greece	nr	nr	Sweden	yes	yes
Hungary	no	no	Switzerland	ns	ns
Iceland	no	no	Turkey	nr	nr
Ireland	ns	ns	Ukraine	nr	nr
Italy	no	no	United Kingdom	yes	no
Latvia	nr	nr	Australia	yes	yes
Liechtenstein	nr	nr	Canada	ns	ns
Lithuania	nr	nr	New Zealand	ns	ns
Luxembourg	nr	nr	United States	ns	ns
Malta	nr	nr			

<u>Germany</u>: In principle the child has the right to know who his parents are (See Constitutional Court's case law BVerfGE 79, 256, 269; 90, 263, 271).

<u>Netherlands</u>: This kind of question is to be considered in view of new legislation.

<u>United States</u>: Increasingly both ovum and sperm donors are being asked to consent to donor identification.

II - THE EMBRYO AND THE FOETUS

- 93. Is there any legislation defining the embryo or the foetus? (y/n)
- [94. If so, could you go into details regarding this definition? (y/n)

a) for the embryo?b) for the foetus?]

95. If there is no legislation at the moment, is legislation planned? (y/n)

Country	93	95	Country	93	95
Austria	yes*	/	Netherlands	no	yes*
Belgium	no	no	Norway	no	no
Bulgaria	no	no	Poland	no	ns
Cyprus	no	no	Portugal	no	yes
Czech Rep.	no	ns	Romania	no	ns
Denmark	no	no	Russia	no	ns
Estonia	no	yes	San Marino	no	ns
Finland	no	yes*	Slovakia	yes	yes
France	no*		Slovenia	yes*	/
Germany	yes*	/	Spain	yes*	/
Greece	no	ns	Sweden	no	no
Hungary	no	no	Switzerland	no*	yes
Iceland	yes*	/	Turkey	no*	ns
Ireland	no	no	Ukraine	no	ns
Italy	no	yes*	United Kingdom	yes*	/
Latvia	no	yes	Australia	no*	no
Liechtenstein	no	no	Canada	no*	yes
Lithuania	no	yes	New Zealand	no	no
Luxembourg	no	no	United States	yes	/
Malta	no	yes*			

- 136 -

<u>Austria</u>: Instead of "embryo", the FMedG (Fortplanzungsmedizingesetz) uses the term "developable cells", defined in section 1 (3) as inseminated ova and cells developed from them.

<u>Germany</u>: According to Section 8 of the Embryo Protection Act, a fertilised, viable human ovum is considered an embryo from the time of karyogamy. The same applies to every totipotent cell taken from an embryo which is capable of division and development into an individual. During the first 24 hours after karyogamy, a human ovum is deemed viable unless it is established before this period of time has elapsed that the human ovum concerned is not capable of developing further that one cell stage.

Finland: Bill concerning medical research on human beings, embryos and foetuses.

<u>France</u>: The embryo is not defined. Article 16 of the Civil Code ensures the protection of the human being from the beginning of life.

Iceland: Icelandic legislation on medically-assisted procreation No.55/1996.

<u>Italy</u>: A bill being examined by the Senate Health Commission contains a general provision concerning interventions and research on the embryo.

Malta: Legislation is planned but no information is available as yet.

<u>Netherlands</u>: There is a preliminary draft concerning i. e. research on the embryo, which is believed to provide for a biological definition of the embryo.

<u>Slovenia</u>: In the Bill on treatment for infertility and on fertilisation with biomedical assistance, the preimplantation embryo is defined as "early embryo". No distinction is made, for the purpose of this law, between post-implantation embryo and foetus.

<u>Spain</u>: The embryo is defined in laws 35/1988 and 42/1988 by reference to the process of organogenesis, or formation of human organs, which continues for about two and a half months thereafter.

<u>Switzerland</u>: The draft of the federal law on M-A.P defines the embryo as the product of fusion of the nuclei up to the completion of organogenesis.

<u>Turkey</u>: A definition is afforded by medical practice; the term "embryo" is used up to the 12th week and "foetus" thereafter.

<u>United Kingdom</u>: The Human Fertilisation and Embryology Act gives some indications. Under its terms, an embryo is a live embryo once fertilisation is completed.

Australia: The Infertility (Medical Procedures) Act of 1984 fails to define "embryo".

<u>Canada</u>: The Supreme Court of Canada has ruled that a fetus does not become a legal person until live birth occurs.

- 96. Is there legislation governing diagnostic activities:
 - a) on embryos in vitro? (y/n)
 - b) on embryos in vivo or on foetuses? (y/n)
- 97. a) If yes, is it a law? (y/n) If so, cite the legislationb) If not, are there professional codes? (y/n)

Country	96a	96b	97a	97b	Country	96a	96b	97a	97b
Austria	у	n	/*	n	Netherlands	n	*	n	у
Belgium	n	n	/	/	Norway	у	у	*	n
Bulgaria	n	n	/	/	Poland	n	у	n	n*
Cyprus	n	n	/	/	Portugal	n	n	/	/
Czech Rep.	n	n	/	/	Romania	n	n	/	/
Denmark	у	n*	y**	n	Russia	n	n	/	/
Estonia	n	n	/	/	San Marino	n	n	/	/
Finland	n	n	/	/	Slovakia	у	у	*	*
France	у	у	у*	/	Slovenia	у	у	*	*
Germany	у	n	у*	у*	Spain	у	у	y*	/
Greece	n	n	/	n	Sweden	ns	у	n	n*
Hungary	n	у	n*	n	Switzerland	n	n	/	/
Iceland	у	у	у*	/	Turkey	n	у	n	y*
Ireland	у	n	*	*	Ukraine	n	n	/	/
Italy	n	n	/	/	United Kingdom	у	n	*	n
Latvia	nr	nr	nr	nr	Australia	у	у	*	ns
Liechtenstein	n	n	/	/	Canada	n	n	/	ns
Lithuania	n	n	n	n	New Zealand	n	n	/	ns
Luxembourg	n	n	/	/	United States	n	n	/	ns
Malta	n	n	/	/					

<u>Austria</u>: Section 9 (1) FMedG provides that embryos may be examined and treated to the necessary extent determined by the state of medical science and experience, to induce a pregnancy.

Denmark: * There are professional codes relating to the Medical Practice Act.

** §7: 1. Genetic examination of a fertilised ovum shall be made only in instances where there is a known and considerably increased risk that the child will have serious hereditary disease.

2. Moreover genetic examination may be made in connection with artificial procreation outside the woman's body because of infertility where such an examination can demonstrate or exclude a considerably chromosome abnormality.

<u>France</u>: Article L162-16 of the Public Health Code provides that antenatal diagnosis comprises procedures with the aim of detecting a disorder of particular gravity in the embryo or foetus in utero. According to Article L162-17 of the Code, pre-implantation diagnosis is authorised only by way of an

According to Article L162-17 of the Code, pre-implantation diagnosis is authorised only by way of an exception on the ground of the likelihood that the couple will have a child afflicted with an incurable genetic disease.

<u>Germany</u>: According to the Protection of the Human Embryo Act pre-implantation diagnosis in respect of totipotent cells is prohibited. According to Section 1 (5) of the MBO (Musterberufsordnung für die deutschen Ärzte), diagnostic activities affecting embryos prior to transfer into the uterus are normally prohibited. An exception is made for activities aimed at excluding serious sex-linked diseases in the unborn child.

<u>Hungary</u>: Not legislation, but decree No. 33 of 23 December 1992 by the Minister for Social Welfare concerning antenatal care, which is the basis for pre-implantation diagnosis practice.

Iceland: Icelandic legislation on medically-assisted procreation No.55/1996.

Ireland: Medical Council guidelines.

<u>Netherlands</u>: Activities are regulated indirectly. Centres performing IVF may conduct pre-implantation diagnosis.

Norway: Act relating to the Application of Biotechnology in Medicine, 1994.

<u>Poland</u>: Antenatal diagnosis on embryo, authorised by Article 23b PPC (Polish Penal Code), can be performed in three cases only: hereditary disease in the parents; fear of a hereditary disease treatable during pregnancy; fear of severe damage to the embryo.

Slovakia: Ethics Committees of the Ministry of health of Slovakia, Medical Faculty, etc....

<u>Slovenia</u>: Bill on treatment for infertility and on fertilisation with biomedical assistance (1997); Gene technology Bill (1997); Code of conduct in MAP (1996).

Spain: Under Article 5 of Law 42/1988, any act performed on an embryo or foetus must have a therapeutic or diagnostic aim.

Law 35/1988, Article 12, provides that antenatal diagnoses on an embryo or foetus in utero or outside are unlawful except where performed for the child's direct benefit or to foster its development, or only in cases expressly permitted by law. Article 13 establishes the same principle in respect of therapeutic interventions

on the embryo and foetus.

Sweden: The guidelines on the application of prenatal diagnosis, adopted by parliament.

<u>Turkey</u>: Rules of professional conduct.

United Kingdom: The Human Fertilisation and Embryology Act.

<u>Australia</u>: See Human Reproductive Technology Act 1991.

98. Is there legislation controlling:a) ante-natal diagnosis? (y/n)b) pre-implantation diagnosis? (y/n)

Country	а	b	Country	a	b
Austria	yes	yes	Netherlands	no	no
Belgium	no	no	Norway	yes	yes
Bulgaria	no	no	Poland	no*	ns
Cyprus	no	no	Portugal	no	no
Czech Rep.	no	no	Romania	no	no
Denmark	no	yes*	Russia	no	no
Estonia	no	no	San Marino	no	no
Finland	no	no	Slovakia	yes	yes
France	yes	yes	Slovenia	yes	yes
Germany	*	*	Spain	yes	yes
Greece	yes	no	Sweden	yes	yes
Hungary	no*	no	Switzerland	no	no*
Iceland	yes	yes	Turkey	no	no*
Ireland	no	no	Ukraine	no	no
Italy	no*	ns	United Kingdom	no	no
Latvia	yes	no	Australia	yes	yes
Liechtenstein	no	no	Canada	no	no
Lithuania	no	no	New Zealand	no	no
Luxembourg	no	no	United States	no	no
Malta	no	no			

<u>Denmark</u>: 1. Genetic examination of a fertilised ovum shall be made only in instances where there is a known and considerably increased risk that the child will have serious hereditary disease.

2. Moreover genetic examination may be made in connection with artificial procreation outside the woman's body because of infertility where such an examination can demonstrate or exclude a considerably chromosome abnormality.

<u>Germany</u>: According to the Protection of the Human Embryo Act pre-implantation diagnosis in respect of totipotent cells is prohibited. According to Section 1 (5) of the MBO (Musterberufsordnung für die deutschen Ärzte), diagnostic activities affecting embryos prior to transfer into the uterus are normally prohibited. An exception is made for activities aimed at excluding serious sex-linked diseases in the unborn child.

Hungary: Not legislation, but decree No. 33 of 23 December 1992.

Italy: No regulations, but the technique is widely used in practice.

<u>Poland</u>: Antenatal diagnosis on embryo, authorised by Article 23b PPC (Polish Penal Code), can be performed in three cases only: hereditary disease in the parents; fear of a hereditary disease treatable during pregnancy; fear of severe damage to the embryo.

<u>Switzerland</u>: The bill prohibits pre-implantation diagnosis and prescribes a criminal sanction. The prenatal diagnosis should be regulated by the law on human genetic analysis, being elaborated at the moment.

<u>Turkey</u>: Pre-implantation diagnosis is not practised.

- 99. May centres performing ante-natal diagnosis:
 - a) practice pre-implantation diagnosis, without there being conditions attached? (y/n)
 - b) practice pre-implantation diagnosis with special authorisation? (y/n)

Country	а	b	Country	a	b
Austria	no	no	Netherlands	ns	ns
Belgium	nr	nr	Norway	no	yes
Bulgaria	nr	nr	Poland	ns	ns
Cyprus	nr	nr	Portugal	nr	nr
Czech Rep.	nr	nr	Romania	nr	nr
Denmark	yes*	no	Russia	nr	nr
Estonia	no	yes	San Marino	nr	nr
Finland	yes	no	Slovakia	no	yes
France	no	yes	Slovenia	no	yes
Germany	no	no	Spain	no	yes
Greece	nr	nr	Sweden	no	yes
Hungary	ns	ns	Switzerland	nr	nr
Iceland	no	ns	Turkey	nr	nr
Ireland	ns	ns	Ukraine	nr	nr
Italy	ns	ns	United Kingdom	no	yes
Latvia	nr	nr	Australia	no	yes
Liechtenstein	nr	nr	Canada	nr	nr
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	yes	/
Malta	nr	nr			

Denmark: In theory, yes.

- 144 -

- 100. Does legislation require authorisation for carrying out embryo research activities? (y/n)
- [101. If authorisation is necessary, which authority is responsible for granting it? (Please specify)]
- 102. If not, are nevertheless specific conditions to be satisfied for carrying out embryo research? (y/n)

Country	100	102	Country	100	102
Austria	/*	/	Netherlands	no	no*
Belgium	nr	nr	Norway	no*	ns
Bulgaria	nr	nr	Poland	ns	ns
Cyprus	nr	nr	Portugal	nr	nr
Czech Rep.	nr	nr	Romania	nr	nr
Denmark	no*	yes**	Russia	nr	nr
Estonia	no	yes	San Marino	nr	nr
Finland	no	no	Slovakia	yes*	no
France	yes*	/	Slovenia	yes*	/
Germany	no*	ns	Spain	yes*	/
Greece	nr	nr	Sweden	no	yes*
Hungary	ns	ns	Switzerland	no*	
Iceland	yes*	/	Turkey	no	ns
Ireland	ns	ns	Ukraine	nr	nr
Italy	nr*		United Kingdom	yes*	/
Latvia	no	nr	Australia	yes	/
Liechtenstein	nr	nr	Canada	no*	/
Lithuania	nr	nr	New Zealand	nr	/
Luxembourg	nr	nr	United States	no	yes*
Malta	nr	nr			
- 145 -

<u>Austria</u>: Sperm and viable cells may be examined and processed only within the necessary limits of the most advanced medical science and experience for the purpose of inducing a pregnancy.

<u>Denmark</u>: * Specific permission need not be obtained for activities involving research on embryos, but control is applied by means of general procedures for the approval of scientific activities from the ethical angle.

** A law institutes a system of scientific ethical committee where biomedical research is conducted on humans.

<u>France</u>: Studies for medical purposes which do not harm embryos and may be carried out on embryos in vitro may only be authorised by the Minister for Health only with the approval of the National Commission for Reproductive Medicine and Biology. On the other hand, research carried out on embryos in vivo is governed by the rules on such biomedical research as may be undergone by pregnant women. This type of research may only be carried out following the approval of one of the regional advisory committees for the protection of persons involved in biomedical research.

<u>Germany</u>: Research on an embryo is prohibited where it does not serve the purpose of preserving the embryo concerned.

Iceland: Authorisation given by Ministry of Health.

<u>Italy</u>: In a 1992 opinion, the National Bioethics Committee called for regulations to limit over-use of this technique and assign responsibility for its application to specialised centres.

<u>Netherlands</u>: There is no existing legislation. However the draft proposes to stipulate approval of research plans by the Ethical Committee at national level.

Norway: Research on embryos is prohibited by law.

Slovakia: Ministry of Health of the Slovak Republic.

Slovenia: The authorization is conferred by the National Medical Ethics Committee.

<u>Spain</u>: Research and experimentation on pre-embryonic life are subject to the condition that the written consent of the subjects be obtained after detailed explanation of the aims and implications of the research.

Sweden: The applicable rules are the general rules of professional conduct.

<u>Switzerland</u>: Research on the human embryo is prohibited because it is not permitted to develop outside the woman's body a greater number of human ova than can be immediately implanted.

<u>United Kingdom</u>: Specific authorisation from the Human Fertilisation and Embryology Authority and also approval from the Local Research Ethics Committee are required.

<u>Canada</u>: Although there is no existing legislation, House Bill C-47 contains some prohibitions concerning embryo research.

United States: Specific conditions attach to federally funded embryo research.

103. Does national legislation provide for specific sanctions in cases of violation of the principles governing embryo research? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	no*
Belgium	no	Norway	yes*
Bulgaria	nr	Poland	ns
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	yes	Russia	nr
Estonia	nr*	San Marino	nr
Finland	no	Slovakia	yes
France	yes	Slovenia	yes
Germany	yes	Spain	yes
Greece	nr	Sweden	no
Hungary	ns	Switzerland	yes*
Iceland	yes	Turkey	nr
Ireland	yes*	Ukraine	nr
Italy	nr	United Kingdom	yes
Latvia	no	Australia	ns
Liechtenstein	nr	Canada	no*
Lithuania	no	New Zealand	nr
Luxembourg	nr	United States	ns
Malta	nr		

Estonia : According to the draft law.

Ireland: Only in connection with Medical Council sanctions.

<u>Netherlands</u>: The bill provides for sanctions in case of violation of principles governing research.

Norway: The Act provides for sanctions in case of violation the ban on embryo research.

<u>Switzerland</u>: The draft law envisages a ban on production of an embryo for any other purpose than implantation, with a prison sentence for infringement.

Canada: The bill provides for sanctions.

- 149 -

104.

Are there committees responsible for overseeing embryo research? (y/n)

Country	Rep.	Country	Rep.
Austria	/	Netherlands	nr
Belgium	nr	Norway	no
Bulgaria	nr	Poland	no
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	yes	Russia	nr
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	yes
France	yes*	Slovenia	yes*
Germany	yes*	Spain	yes*
Greece	nr*	Sweden	nr
Hungary	ns	Switzerland	no*
Iceland	yes*	Turkey	yes
Ireland	ns	Ukraine	nr
Italy	no	United Kingdom	yes
Latvia	nr	Australia	yes
Liechtenstein	nr	Canada	yes
Lithuania	no	New Zealand	ns
Luxembourg	nr	United States	yes
Malta	nr		

<u>France</u>: The National Commission for Reproductive Medicine and Biology is responsible for overseeing research on embryos in vitro and the advisory committees for the protection of persons involved in biomedical research are responsible for overseeing research likely to be carried out on pregnant women and therefore that involving embryos in vivo.

<u>Germany</u>: Research on an embryo is prohibited where it does not serve the purpose of preserving the embryo concerned. Experiments on embryos serving the purpose of preserving the same may require consideration by an Ethics Committee.

<u>Greece</u>: In principle, scientific committee of the hospitals would oversee embryo research done in their hospitals.

Iceland: Not been appointed yet.

<u>Slovenia</u>: The National Medical Ethics Committee. In addition, according to the law, all activities within the field of M-AP are monitored by a State Committee for fertilisation with biomedical assistance.

<u>Spain</u>: The law refers to a national multidisciplinary commission and a national commission for follow-up and control. The code of medical ethics stipulates that biomedical research projects involving humans are to be approved by the commission on ethics and clinical research and must fulfil the ethical guarantees required by the medical association.

Switzerland: The draft law prescribes the establishment of a national ethics committee.

105. Are these committees multidisciplinary? (y/n)

Country	Rep.	Country	Rep.
Austria	/	Netherlands	nr
Belgium	nr	Norway	ns
Bulgaria	nr	Poland	nr
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	yes	Russia	nr
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	yes
France	yes	Slovenia	yes
Germany	yes	Spain	yes
Greece	nr	Sweden	yes
Hungary	ns	Switzerland	yes
Iceland	ns	Turkey	yes
Ireland	ns	Ukraine	nr
Italy	nr	United Kingdom	yes
Latvia	yes	Australia	yes
Liechtenstein	nr	Canada	yes
Lithuania	/	New Zealand	ns
Luxembourg	nr	United States	yes
Malta	nr		

Do the responsibilities of these committees include an ethical dimension? (y/n)

Country	Rep.	Country	Rep.
Austria	/	Netherlands	*
Belgium	nr	Norway	ns
Bulgaria	nr	Poland	nr
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	yes	Russia	nr
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	yes
France	yes	Slovenia	yes
Germany	yes	Spain	yes
Greece	nr	Sweden	yes
Hungary	ns	Switzerland	yes
Iceland	ns	Turkey	yes
Ireland	ns	Ukraine	nr
Italy	nr	United Kingdom	yes
Latvia	yes	Australia	yes
Liechtenstein	nr	Canada	yes
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	yes
Malta	nr		

<u>Netherlands</u>: It is intended to set up a committee with an ethical dimension.

107. What is the role of these committees:

a) to define a research approach? (y/n)

b) to issue guidelines in the absence of or in addition to legislation? (y/n)

c) to monitor research activities? (y/n)

d) to issue approval of research establishments? (y/n)

e) to inform the public (through advice or information on sterility or genetic diseases)? (y/n)

Country	a	b	c	d	e	Country	а	b	c	d	e
Austria	/	/	/	/	/	Netherlands	nr	nr	nr	nr	nr
Belgium	nr	nr	nr	ns	ns	Norway	ns	ns	ns	ns	ns
Bulgaria	nr	nr	nr	nr	nr	Poland	nr	nr	nr	nr	nr
Cyprus	nr	nr	nr	nr	nr	Portugal	nr	nr	nr	nr	nr
Czech Rep.	nr	nr	nr	nr	nr	Romania	nr	nr	nr	nr	nr
Denmark	n	у	у	n	ns	Russia	nr	nr	nr	nr	nr
Estonia	у	у	у	у	n	San Marino	nr	nr	nr	nr	nr
Finland	n	n	у	n	n	Slovakia	у	у	у	у	у
France	n	n	у	n	n*	Slovenia	n	у	у*	y**	n***
Germany	n*	n	n	n	n	Spain	у	у	у	n	n*
Greece	nr	nr	nr	nr	nr	Sweden	n	n	n	у	n
Hungary	ns	ns	ns	ns	ns	Switzerland	у	у	ns	ns	у
Iceland	ns	ns	ns	ns	ns	Turkey	у	у	у	у	у
Ireland	ns	ns	ns	ns	ns	Ukraine	nr	nr	nr	nr	nr
Italy	nr	nr	nr	nr	nr	United Kingdom	n	у	у	у	у
Latvia	у	у	у	у	n	Australia	у	у	у	у	у
Liechtenstein	/	/	/	/	/	Canada	ns	ns	ns	ns	ns
Lithuania	ns	ns	ns	ns	ns	New Zealand	ns	ns	ns	ns	ns
Luxembourg	nr	nr	nr	nr	nr	United States	у*	у*	у*	у*	у*
Malta	nr	nr	nr	nr	nr						

- 155 -

<u>France</u>: Whilst the National Commission for Reproductive Medicine and Biology has no public information function, it is responsible (under Article L152-8 of the Public Health Code) for publishing an annual list of establishments in which embryo research is being carried out and giving in each case details of the objectives of the research.

Germany: They have an advisory function and they give recommendations in individual cases.

<u>Slovenia</u>: * In some projects, according to the Committee judgment.

** In evaluation of each project, professional standards of the institution as well as medical and scientific qualifications of the research personnel involved is subject to scrutiny. *** Except in special cases.

<u>Spain</u>: Under domestic law, one of the functions of the National Commission for Medically Assisted Human Procreation is to inform and advise the competent health authorities about scientific and technical publicity and advertising campaigns on announcements or similar disclosures that M-A.P centres and theirs services could organize concerning M-A.P.

<u>United States</u>: Only for federally funded research.

108.	Are these committees set up:
	a) at national level? (y/n)
	b) at regional level? (y/n)
	c) at local level? (y/n)

[109. If possible, please indicate their names.]

[110. With regard to the authority mentioned in question 101:a) can these committees form part of that authority? (y/n)b) are these committees separate from it? (y/n)]

Country	108 a	108 b	108 c	Country	108 a	108 b	108 c
Austria	/	/	/	Netherlands	у	nr	nr
Belgium	nr	nr	nr	Norway	ns	ns	ns
Bulgaria	nr	nr	nr	Poland	nr	nr	nr
Cyprus	nr	nr	nr	Portugal	nr	nr	nr
Czech Rep.	nr	nr	nr	Romania	nr	nr	nr
Denmark	у	У	n	Russia	nr	nr	nr
Estonia	n	n	у*	San Marino	nr	nr	nr
Finland	у*	n	y**	Slovakia	у*	у*	y*
France	у	n	n	Slovenia	у	n	у*
Germany	n	у	у	Spain	у	у*	у*
Greece	nr	nr	nr	Sweden	n	у*	n
Hungary	ns	ns	ns	Switzerland	у	ns	ns
Iceland	yes	/	/	Turkey	у	ns	ns
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	nr	nr	nr	United Kingdom	у*	n	у
Latvia	yes*	no	yes*	Australia	У	у	n
Liechtenstein	nr	nr	nr	Canada	ns	ns	ns
Lithuania	/	/	/	New Zealand	ns	ns	ns
Luxembourg	nr	nr	nr	United States	у*	n	n
Malta	nr	nr	nr				

- 157 -

Estonia: Bioethics Committee of the University of Tartu.

<u>Finland</u>: * Research Ethics Committee of the Academy of Finland. ** Research ethics committees in hospitals.

Latvia: Central Medical Ethics Committee in Medical Research, Ethics Committee of Laboratory Animals Use, Committees on clinical trials.

Slovakia: Council of Science of Ministry of Health, Medical Faculty.

<u>Slovenia</u>: After approval by the National Medical Ethics Committee, the follow-up of some research projects is entrusted to the institutional review board, which is responsible for the observance of ethical and legal principles throughout the research. These institutional review boards are not represented in the National Medical Ethics Committee.

<u>Spain</u>: In addition to the National Commission for Medically Assisted Human Procreation, the law authorizes the creation of similar commissions in the autonomous regions as well as in approved centres or services.

Sweden: Such committees are set up in every medical faculty.

<u>United Kingdom</u>: The Human Fertilisation and Embryology Authority, the same body as the one responsible for authorising the embryo research project.

<u>United States</u>: Only for federally funded research.

111. Are the medical teams obliged to inform the committee of the results of their work? (y/n)

Country	Rep.	Country	Rep.
Austria	/	Netherlands	*
Belgium	nr	Norway	ns
Bulgaria	nr	Poland	nr
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	yes	Russia	nr
Estonia	yes	San Marino	nr
Finland	no	Slovakia	no
France	ns	Slovenia	yes*
Germany	ns	Spain	yes
Greece	nr	Sweden	no
Hungary	ns	Switzerland	ns
Iceland	ns	Turkey	yes
Ireland	ns	Ukraine	nr
Italy	nr	United Kingdom	yes*
Latvia	ns	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	/	New Zealand	ns
Luxembourg	nr	United States	ns
Malta	nr		

- 159 -

<u>Netherlands</u>: The medical teams will not be required to inform the ethics committee of the results of their research.

<u>Slovenia</u>: Upon the request of the Committee, usually only in cases of studies which are considered to present appreciable risk to the embryo, foetus or pregnant woman.

<u>United Kingdom</u>: As instructed by the Human Fertilisation and Embryology Authority.

- 160 -

112. Are there either legislation or codes of practice governing therapeutic research:

a) on embryos in vitro? (y/n)
b) on embryos in vivo? (y/n)
c) on foetuses? (y/n)

[113. If so, what is the legal nature of either legislation or codes of practice concerning:

a) embryos in vitro?b) embryos in vivo?

c) foetuses?]

Country	112a	112b	112c	Country	112a	112b	112c
Austria	yes*	yes	ns	Netherlands	*	*	*
Belgium	no	no	no	Norway	ns	no	no
Bulgaria	no	no	no	Poland	yes*	yes	yes
Cyprus	no	no	no	Portugal	no	no	no
Czech Rep.	no	no	no	Romania	no	no	no
Denmark	yes*	yes*	yes*	Russia	no	no	no
Estonia	no	no	no	San Marino	no	no	no
Finland	no	no	no	Slovakia	yes	yes	yes
France	yes*	yes	yes	Slovenia	yes*	yes*	yes*
Germany	yes	nr	nr	Spain	yes*	yes	yes
Greece	no	no	no	Sweden	no	no	no
Hungary	no	no	no	Switzerland	ns	ns	ns
Iceland	yes*	yes*	yes*	Turkey	nr*	nr*	nr
Ireland	yes*	yes*	yes*	Ukraine	no	no	no
Italy	no	no	no	United Kingdom	yes*	yes**	yes**
Latvia	nr	nr	nr	Australia	у	у	у
Liechtenstein	no	no	no	Canada	у*	у	у
Lithuania	no	no	no	New Zealand	nr	nr	nr
Luxembourg	no	no	no	United States	у	у	у
Malta	no	no	no				

<u>Austria</u>: Section 9 FMedG states the general principle that embryos must not be used for any other purpose than M-A.P. Sperm and viable cells may be examined and processed only within the necessary limits of the most advanced medical science and experience for the purpose of inducing a pregnancy.

<u>Denmark</u>: The law concerning a system of Scientific Ethics Committees and biomedical experimentation on human beings.

<u>France</u>: The rules applicable to therapeutic research are not specific to it. Regarding embryos in vitro, French legislation merely makes a distinction between research for medical purposes which does not harm the embryo and may be authorised, and other types of research, which are prohibited. Research for medical purposes need not be therapeutic. Regarding embryos in utero and foetuses, the law draws a distinction between research which can be expected to be of direct personal benefit to the person undergoing it (the mother) and research which has no direct personal benefit and can only be carried out if it poses no foreseeable serious threat to health of the mother or the child, makes a useful contribution to knowledge about pregnancy and cannot be carried out otherwise.

Germany: Protection of the Human Embryo Act.

Iceland: Icelandic legislation on medically-assisted procreation No. 55/1996.

Ireland: The Medical Council guidelines.

<u>Netherlands</u>: No statutory regulations, but a code of conduct. The same applies to research on foetuses. In either case, the research plans are submitted voluntarily to a provisional central committee.

Poland: Therapeutic research is permissible under Article 23b PCC (Polish Civil Code).

<u>Slovenia</u>: Code of conduct in M-AP, partly also the Bill on treatment for infertility and on fertilisation with biomedical assistance, Gene technology Bill, and the rules of the National Medical Ethics Committee (drafting a bill on biomedical research in human beings, also covering research on embryo and foetus, is envisaged).

<u>Spain</u>: In principle, experimentation on pre-embryos is prohibited by section 16 of Law 35/1988. Section 12 of that law provides that research on a pre-embryo in vitro shall be permitted only if it has diagnostic value and therapeutic or prophylactic aims and if the non-pathological genetic inheritance remains unchanged.

The code of medical ethics, Article 32, provides that the risks and disorders resulting from research on human beings must not be disproportionate or offend the patient's morality and dignity.

Law No. 42/1988 contains provisions authorising research on embryos and foetuses or on their biological structure. Such research is authorised only for diagnostic and therapeutic purposes and must be carried out by qualified biomedical teams in approved centres or services under official supervision.

<u>Turkey</u>: Research is permitted on animals only.

<u>United Kingdom</u>: * The Human Fertilisation and Embryology Act. ** This would be covered by codes of practice on therapeutic research in human beings. -----

Canada: Only codes of practice exist. House Bill C-47 may contain provisions.

114.

Is therapeutic research lawful on:

a) embryos in vitro? (y/n)b) embryos in vivo? (y/n)c) foetuses? (y/n)

Country	114a	114b	114c	Country	114a	114b	114c
Austria	у	у	у	Netherlands	*	*	*
Belgium	nr	nr	nr	Norway	n	у	у
Bulgaria	nr	nr	nr	Poland	у	у	у
Cyprus	nr	nr	nr	Portugal	nr	nr	nr
Czech Rep.	nr	nr	nr	Romania	nr	nr	nr
Denmark	у*	у*	у*	Russia	nr	nr	nr
Estonia	n	n	n	San Marino	nr	nr	nr
Finland	у	у	у	Slovakia	у	у	у
France	у*	у*	у*	Slovenia	у*	у*	у*
Germany	у	у	у	Spain	у	у	у
Greece	nr	nr	nr	Sweden	у	ns	у
Hungary	nr	nr	nr	Switzerland	n	n	n
Iceland	*	*	*	Turkey	n	n	n
Ireland	n	n	n	Ukraine	nr	nr	nr
Italy	nr	nr	nr	United Kingdom	у*	у	у
Latvia	nr	nr	nr	Australia	n*	n**	ns
Liechtenstein	nr	nr	nr	Canada	nr	nr	nr
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	у	у	у*
Malta	nr*	nr	nr				

- 164 -

Denmark: Subject to the approval of the Central Science Ethics Committee.

<u>France</u>: The rules applicable to therapeutic research are not specific to it. Regarding embryos in vitro, French legislation merely makes a distinction between research for medical purposes which does not harm the embryo and may be authorised, and other types of research, which are prohibited. Research for medical purposes need not be therapeutic. Regarding embryos in utero and foetuses, the law draws a distinction between research which can be expected to be of direct personal benefit to the person undergoing it (the mother) and research which has no direct personal benefit and can only be carried out if it poses no foreseeable serious threat to health of the mother or the child, makes a useful contribution to knowledge about pregnancy and cannot be carried out otherwise.

<u>Iceland</u>: The general rule is that all research on embryos is research. However the following exceptions are detailed in the law:

- 1. research that is a part of an in-vitro fertilization treatment;
- 2. research aimed at diagnosing hereditary diseases in the embryo;
- 3. research aimed at development in the treatment of infertility or,

4. research in order to increase understudying of the reasons for hereditary diseases and miscarriage.

Malta: No such research is conducted and if so would be prohibited by analogy with abortion.

<u>Netherlands</u>: Not yet officially regulated. No statutory regulations, but a code of conduct. The same applies to research on foetuses. In either case, the research plans are submitted voluntarily to a provisional central committee.

<u>Slovenia</u>: In vitro research on surplus embryos is allowed provided that they have not been allowed to develop beyond 14 days or the stage of primitive crest. On embryos in vivo or foetuses, in principle only such research is lawful which has the potential to benefit their health.

<u>United Kingdom</u>: Subject to the authorisation of the Human Fertilisation and Embryology Authority.

<u>Australia</u>: * It is unlawful in Western Australia to conduct research from in vitro fertilisation. ** It is unlawful in Western Australia to conduct research on an egg which is fertilising or an embryo unless approval has been granted by the Reproductive Technology Council.

<u>United States</u>: Certain states have laws controlling research on aborted foetuses. For instance, Rhode Island permits therapeutic research on the foetus.

-	165	-
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115.Is embryo research lawful:

a) for all types of disease? (y/n)b) for certain types of disease? (y/n)

[116. If you have answered yes to b), please indicate the diseases.]

117. Is research on foetuses lawful:

a) for all types of disease? (y/n)b) for certain types of disease? (y/n)

[118. If you have answered yes to b), please indicate the diseases.]

Country	115a	115b	117a	117 b	Country	115 a	115b	117 a	117b
Austria	no	yes*	no	yes*	Netherlands	no	yes*	yes	/
Belgium	nr	nr	nr	nr	Norway	nr	nr	nr	nr
Bulgaria	nr	nr	nr	nr	Poland	no	yes*	no	yes*
Cyprus	nr	nr	nr	nr	Portugal	nr	nr	nr	nr
Czech Rep.	ns	ns	nr	nr	Romania	nr	nr	nr	nr
Denmark	no	yes*	**	/	Russia	nr	nr	nr	nr
Estonia	no	no	no	no	San Marino	nr	nr	nr	nr
Finland	yes	/	yes	/	Slovakia	no	yes*	no	yes*
France	nr*	nr*	nr*	nr*	Slovenia	nr*	nr*	nr**	nr**
Germany	yes	no	yes	no	Spain	yes	/	yes	/
Greece	nr	nr	nr	nr	Sweden	yes	/	yes	/
Hungary	nr	nr	nr	nr	Switzerland	no	no	no	no
Iceland	*	*	*	*	Turkey	nr	nr	nr	nr
Ireland	no	no	no	no	Ukraine	nr	nr	nr	nr
Italy	nr	nr	nr	nr	United Kingdom	yes*	/	yes	/
Latvia	nr	nr	nr	nr	Australia	ns	ns	ns	ns
Liechtenstein	nr	nr	nr	nr	Canada	nr	nr	nr	nr
Lithuania	nr	nr	nr	nr	New Zealand	nr	nr	nr	nr
Luxembourg	nr	nr	nr	nr	United States	ns	ns	no	yes*
Malta	nr	nr	nr	nr					

Austria: Research on embryos and foetuses may be performed for no other purpose than M-A.P.

<u>Denmark</u>: * Research on embryos is allowed only for the purpose of improving either the fertilising efficiency of in vitro treatment or of improving techniques for genetic investigation. ** Subject to the approval of the Central Science Ethics Committee.

<u>France</u>: Under French law the lawfulness of actual research work on embryos and foetuses does not depend on the type of disease. However, the type of disease does constitute a precondition:

1. for cytogenetic or biological analyses aimed at establishing an antenatal diagnosis. The only permissible objective of this type of analysis is to detect in embryos or foetuses in utero particularly serious ailments which have been medically proved, prior to the diagnosis, to pose a threat to the unborn child;

2. for pre-implantation diagnosis. This is only allowed if it is medically certified that the couple has a high probability of producing a child with a particularly serious genetic disease, recognised as incurable at the time of diagnosis.

<u>Iceland</u>: The general rule is that all research on embryos is research. However the following exceptions are detailed in the law:

- 1. research that is a part of an in-vitro fertilization treatment.
- 2. research aimed at diagnosing hereditary diseases in the embryo.
- 3. research aimed at development in the treatment of infertility or

4. research in order to increase understudying of the reasons for hereditary diseases and miscarriage.

<u>Netherlands</u>: To improve knowledge relating to M-A.P and treatment of infertility and hereditary or congenital diseases. But not legally regulated as yet.

Poland: Permitted for hereditary diseases and serious risks.

<u>Slovakia</u>: Genetic, congenital development error.

<u>Slovenia</u>: * There are no specific statutory regulations regarding the types of disorders. The judgment as to the ethical acceptability is left to the judgment of the National Medical Ethics Committee. Any research without the approval of this Committee would be illegal. ** Also on this question, there are no specific statutory regulations.

<u>United Kingdom</u>: Embryo research in vitro may be carried out for purposes specified in a schedule to the Human Fertilisation and Embryology Act 1990. Research in vivo is covered by codes of research practice.

<u>United States</u>: Some states have legislated on research on foetuses.

9. Is it lawful to intervene for the purpose of selecting the sex of the foetus or the embryo in the case of a disease linked to the sex chromosomes? (y/n)

Country	Rep.	Country	Rep.
Austria	no	Netherlands	nr
Belgium	nr	Norway	yes
Bulgaria	nr	Poland	no
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	yes	Russia	nr
Estonia	yes	San Marino	nr
Finland	yes	Slovakia	no
France	yes	Slovenia	yes
Germany	yes*	Spain	yes
Greece	nr	Sweden	yes
Hungary	nr	Switzerland	non*
Iceland	ns	Turkey	ns
Ireland	no	Ukraine	nr
Italy	nr	United Kingdom	yes
Latvia	no	Australia	yes
Liechtenstein	nr	Canada	nr*
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	yes
Malta	nr*		

119.

- 168 -

<u>Germany</u>: Choosing the sex of the future embryo by choosing a sperm cell is not prohibited if this serves the purpose of safeguarding the child against contracting a muscular dystrophy of the Duchenne type or a serious sexually determined hereditary disease and if the disease with which the child is threatened has been recognised as a similarly serious disease by the agency competent to do so pursuant to Land law.

Malta: Prohibited by analogy with abortion.

Switzerland: The pre-implantation diagnosis is prohibited. This prohibition is nevertheless debated.

<u>Canada</u>: House Bill C-47 prohibits using any medical procedure for the purpose of ensuring, or increasing the probability, that a zygote or embryo will be of a particular sex, except for reasons related to the health of the zygote or embryo.

- 169 -

120. Is therapeutic intervention on the germ cell line:

a) lawful in general? (y/n)b) prohibited in general? (y/n)c) lawful in exceptional cases? (y/n)

[121. If you have answered yes to c), please give details]

Country	а	b	с	Country	a	b	с
Austria	no	yes	no	Netherlands	no	*	*
Belgium	nr	nr	nr	Norway	no	yes	no
Bulgaria	nr	nr	nr	Poland	no	yes	no
Cyprus	nr	nr	nr	Portugal	nr	nr	nr
Czech Rep.	nr	nr	nr	Romania	nr	nr	nr
Denmark	yes*	no	no*	Russia	nr	nr	nr
Estonia	no	no	no	San Marino	nr	nr	nr
Finland	ns	ns	ns	Slovakia	yes	no	no
France	no	yes	yes*	Slovenia	no	yes	no*
Germany	no	yes	no	Spain	no	yes	yes*
Greece	nr	nr	nr	Sweden	no	yes	ns
Hungary	nr	nr	nr	Switzerland	no	yes	no*
Iceland	ns	ns	ns	Turkey	nr*	nr	nr
Ireland	no	yes	no	Ukraine	nr	nr	nr
Italy	nr*	nr	nr	United Kingdom	no*	no*	ns
Latvia	nr	nr	nr	Australia	no	no	yes
Liechtenstein	nr	nr	nr	Canada	nr	nr	nr
Lithuania	nr	nr	nr	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	nr	nr	nr
Malta	no	no	no				

<u>Denmark</u>: It is not lawful to start using new methods of treatment and diagnostic etc..., in connection with artificial procreation until the Minister of Health has approved hereof in relation to medical and ethical considerations. Therapeutic intervention on the germ cell line has not yet been done in Denmark.

<u>France</u>: The research authorised is that aimed at the prevention and treatment of diseases. Genetic characteristics may not be altered for the purpose of modifying the person's offspring.

<u>Italy</u>: Article 3 (1) of the bill prohibits all intervention on the embryo which is not for diagnostic or therapeutic purposes.

<u>Netherlands</u>: It is intended to prohibit this explicitly.

<u>Slovenia</u>: However, the Gene Technology Bill contains a provision that germ cell line therapy is prohibited until such time as new developments in medical science would allow for safe intervention, without risk of introducing unwanted changes in genetically transmissible traits. Somatic gene therapy is, in principle, allowed only when there is no risk of introducing a genetic modification to patient's descendants.

<u>Spain</u>: Interventions for diagnostic or therapeutic purposes are permitted providing that the non-pathological germ cell line is not modified.

<u>Switzerland</u>: This prohibition does not apply to cases where the germ cell line has been incidentally modified as a result of medical treatment.

Turkey: Performed on animals.

<u>United Kingdom</u>: Such research on embryos in vitro is prohibited by the HFE Act 1990 (Schedule 2). There is voluntary abstention from such interventions in vivo in situations not covered by the Act.

122. Is there either legislation or codes of practice governing non-therapeutic research:

a) on embryos in vitro? (y/n)
b) on embryos in vivo? (y/n)
c) on foetuses? (y/n)

[123. If so, what is the legal nature of either legislation or codes of practice concerning:
a) embryos in vitro?
b) embryos in vivo?
c) foetuses?]

Country	122a	122b	122c	Country	122a	122b	122c
Austria	no	no	no	Netherlands	nr	nr*	nr*
Belgium	nr	nr	nr	Norway	*	nr	nr
Bulgaria	nr	nr	nr	Poland	ns	ns	ns
Cyprus	nr	nr	nr	Portugal	no	no	no
Czech Rep.	nr	nr	nr	Romania	nr	nr	nr
Denmark	yes	yes	yes	Russia	nr	nr	nr
Estonia	no	no	no	San Marino	nr	nr	nr
Finland	no	no	no	Slovakia	no	no	no
France	yes	yes	yes*	Slovenia	yes*	no*	no*
Germany	yes*	nr	nr	Spain	yes	yes	yes*
Greece	nr	nr	nr	Sweden	yes	yes	yes
Hungary	nr	nr	nr	Switzerland	nr	nr	nr
Iceland	no	no	no	Turkey	nr	nr	nr
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	nr	nr	nr	United Kingdom	yes*	yes**	yes**
Latvia	nr	nr	nr	Australia	yes	yes	yes
Liechtenstein	nr	nr	nr	Canada	nr*	nr	nr
Lithuania	no	no	no	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes	yes	yes
Malta	nr	nr	nr				

<u>France</u>: The rules applicable to therapeutic research are not specific to it. Regarding embryos in vitro, French legislation merely makes a distinction between research for medical purposes which does not harm the embryo and may be authorised, and other types of research, which are prohibited. Research for medical purposes need not be therapeutic. Regarding embryos in utero and foetuses, the law draws a distinction between research which can be expected to be of direct personal benefit to the person undergoing it (the mother) and research which has no direct personal benefit and can only be carried out if it poses no foreseeable serious threat to health of the mother or the child, makes a useful contribution to knowledge about pregnancy and cannot be carried out otherwise. The applicable rules are contained in Articles L.152-8 (research on embryo in vitro) and L.209-4 (research involving pregnant women) of the Public Health Code.

Germany: Protection of the Human Embryo Act.

<u>Netherlands</u>: Non therapeutic research on embryos/fetuses in vivo is not regulated in legislation as yet and is not admissible in practice.

Norway: Research on embryos in vitro is prohibited.

<u>Slovenia</u>: General principles governing ethical acceptability of biomedical research on human beings apply. In practice, non-therapeutic research involving any risk to viable embryos or foetuses, except surplus in vitro embryos below 14 days of development, would be prohibited. Code of conduct in M-AP, partly also the Bill on treatment for infertility and on fertilisation with biomedical assistance, Gene technology Bill, and the rules of the National Medical Ethics Committee (drafting a bill on biomedical research in human beings, also covering research on embryo and foetus, is envisaged).

<u>Spain</u>: Law 35/1988 makes it a very serious administrative infraction to use the pre-embryo or its cells industrially for other than therapeutic or diagnostic purposes, and in general to conduct research in breach of the statutory provisions. The same applies to research on the foetus.

<u>United Kingdom</u>: * Control is exercised by the Human Fertilisation and Embryology Authority. ** Non-therapeutic research on embryos in vivo and on foetuses in general is deemed unacceptable under the codes of practice.

<u>Canada</u>: The Law Commission of Canada published a Working Paper in 1989, called Biomedical Experimentation Involving Human Subjects, which addresses issues of research.

- 173 -

124. Is non-therapeutic research lawful on:

> a) viable embryos in vitro? (y/n)b) viable embryos in vivo or viable foetuses? (y/n) c) non-viable embryos in vitro? (y/n) d) non-viable embryos in vivo or non-viable foetuses? (y/n) e) embryos in vivo resulting from in vitro fertilisation? (y/n)

[125. What are the criteria for the non-viability:

a) of an embryo?

b) of a foetus?]

Country	124 a	b	c	d	e	Country	124 a	b	c	d	e
Austria	n	n	n	n	n	Netherlands	nr*	nr*	nr*	nr*	nr*
Belgium	nr	nr	nr	nr	nr	Norway	n	n	n	n	n
Bulgaria	nr	nr	nr	nr	nr	Poland	n	n	n	n	n
Cyprus	nr	nr	nr	nr	nr	Portugal	nr	nr	nr	nr	nr
Czech Rep.	nr	nr	nr	nr	nr	Romania	nr	nr	nr	nr	nr
Denmark	у*	у	у	у	у	Russia	nr	nr	nr	nr	nr
Estonia	у	n	у*	n	у	San Marino	nr	nr	nr	nr	nr
Finland	ns	ns	ns	ns	ns	Slovakia	n	n	n	n	n
France	у*	у*	nr	nr	у	Slovenia	n	n	y*	n*	n
Germany	n*	nr**	n	nr**	nr**	Spain	n	n	y*	у*	n
Greece	nr	nr	nr	nr	nr	Sweden	у	у	у*	y*	у
Hungary	nr	nr	nr	nr	nr	Switzerland	n	n	n	n	n
Iceland	n	n	n	n	n	Turkey	nr	nr	nr	nr	nr
Ireland	ns	ns	ns	ns	ns	Ukraine	nr	nr	nr	nr	nr
Italy	nr	nr	nr	nr	nr	United Kingdom	у	у	y*	y*	у
Latvia	nr	nr	nr	nr*	nr	Australia	ns*	ns	ns	ns	ns
Liecht.	nr	nr	nr	nr	nr	Canada	nr*	nr	nr	nr	nr
Lithuania	nr	nr	nr	nr	nr	New Zealand	nr	nr	nr	nr	nr
Luxembourg	nr	nr	nr	nr	nr	United States	n*	n*	у	у	n*
Malta	nr	nr	*	nr	nr						

- 174 -

<u>Denmark</u>: Subject to the approval of the Central Science Ethics Committee and in accordance with statutory restrictions. This is also the doctor's responsibility under the Medical Practices Act.

Estonia: The criterion for non-viability is the destruction of cells.

<u>France</u>: The rules applicable to therapeutic research are not specific to it. Regarding embryos in vitro, French legislation merely makes a distinction between research for medical purposes which does not harm the embryo and may be authorised, and other types of research, which are prohibited. Research for medical purposes need not be therapeutic. Regarding embryos in utero and foetuses, the law draws a distinction between research which can be expected to be of direct personal benefit to the person undergoing it (the mother) and research which has no direct personal benefit and can only be carried out if it poses no foreseeable serious threat to health of the mother or the child, makes a useful contribution to knowledge about pregnancy and cannot be carried out otherwise.

<u>Germany</u>: *According to the "Protection of the Human Embryo Act" there is a criminal liability with up to three years' imprisonment for anyone who sells a human embryo created in vitro or removed from a woman before its complete nidation in the uterus, or for anyone who gives, acquires or uses such an embryo for a purpose not serving its preservation. The same penalty is imposed for causing a human embryo to develop in vitro for any other purpose than to induce pregnancy.

** The Model Professional Code prohibits research on human embryos.

Latvia: The criteria for the non-viability of an embryo is no cleavage and for a foetus is no heart beating.

<u>Malta</u>: No research at present, but could be authorised by law as regards non-therapeutic research on non-viable embryos.

<u>Netherlands</u>: Non therapeutic research on embryos/fetuses in vivo is not regulated in legislation as yet and is not admissible in practice. The already mentioned draft provides for regulation of non therapeutic research on embryos in vitro under strict conditions.

Slovenia: The criteria is "abnormal embryo incapable of further development".

<u>Spain</u>: Research on living embryos or foetuses, whether viable or otherwise not in conformity with the law constitutes a very serious offence, saving when its concerns non-viable embryos or foetuses outside the uterus in conformity with a research project approved by the relevant public authorities or, if appropriate, by the National Commission for Monitoring and Supervision.

Sweden: The criterion for non-viability is absence of heart activity.

<u>United Kingdom</u>: The criterion of non-viability is not defined, however.

<u>Australia</u>: The Infertility (Medical Procedures) (Amendment) Act 1987 permits research that is "reasonably likely to produce information or establish knowledge indication procedures (including fertilisation procedures) that might be carried out for the purpose of enabling a woman who has undergone examination or treatment to become pregnant".

<u>Canada</u>: The Law Commission's recommendations permit non-therapeutic experimentation if certain conditions are met.

<u>United States</u>: Eight States prohibit experimentation on aborted foetuses. Other statutes apply only to "live" or "viable" embryos or foetuses. However, a distinction can be made between early, preimplementation embryos and later ones. Therefore, only Minnesota and New Mexico define "foetus" in a way that could apply to a preimplantation embryo. - 176 -

126.

Is special authorisation necessary for carrying out research on:

a) viable embryos in vitro? (y/n)

b) non-viable embryos in vitro? (y/n)

c) viable embryos in vivo or viable foetuses? (y/n)

d) non-viable embryos in vivo or non-viable foetuses? (y/n)

Country	а	b	с	d	Country	a	b	с	d
Austria	/	/	/	/	Netherlands	nr	nr	nr	nr
Belgium	nr	nr	nr	nr	Norway	nr	nr	nr	/
Bulgaria	nr	nr	nr	nr	Poland	nr	nr	nr	nr
Cyprus	nr	nr	nr	nr	Portugal	nr	nr	nr	nr
Czech Rep.	nr	nr	nr	nr	Romania	nr	nr	nr	nr
Denmark	n	n	n	n	Russia	nr	nr	nr	nr
Estonia	у	у	у	у	San Marino	nr	nr	nr	nr
Finland	n	n	n	n	Slovakia	у	у	у	у
France	у	у	у	у	Slovenia	у	у	у	у
Germany	/	/	/	/	Spain	у	у	у	у
Greece	nr	nr	nr	nr	Sweden	n	n	n	n
Hungary	nr	nr	nr	nr	Switzerland	nr	nr	nr	nr
Iceland	/	/	/	/	Turkey	nr	nr	nr	nr
Ireland	ns	ns	ns	ns	Ukraine	nr	nr	nr	nr
Italy	nr	nr	nr	nr	United Kingdom	у	n	у	у
Latvia	nr	nr	nr	nr	Australia	у*	у*	у*	у*
Liechtenstein	nr	nr	nr	nr	Canada	у*	ns	ns	ns
Lithuania	nr	nr	nr	nr	New Zealand	nr	nr	nr	nr
Luxembourg	nr	nr	nr	nr	United States	у*	у*	у*	у*
Malta	nr	nr	nr	nr					

<u>Australia</u>: The Infertility (Medical Procedures) Act 1984 (Vic) states that an experimental procedure must be approved by the Standing Review and Advisory Committee. No distinction is made in the legislation between non-viable and viable.

<u>Canada</u>: According to the bill, the experimentation would have to receive the prior approval of a multidisciplinary ethics committee responsible for ensuring that the research is ethical and scientifically genuine and having direct authority to monitor and control it.

<u>United States</u>: Regulations apply only to researchers who receive federal funds or who are affiliated with an institution that has signed an agreement with the Department of Health and Human Services.

127. In order to carry out research on dead embryos or foetuses, is it necessary to obtain:

a) only the consent of the mother? (y/n)b) the consent of both parents? (y/n)

Country	а	b	Country	a	b
Austria	ns	ns	Netherlands	nr	nr
Belgium	nr	nr	Norway	ns	ns
Bulgaria	nr	nr	Poland	nr	nr
Cyprus	nr	nr	Portugal	nr	nr
Czech Rep.	nr	nr	Romania	nr	nr
Denmark	no	yes	Russia	nr	nr
Estonia	ns	ns	San Marino	nr	nr
Finland	ns	ns	Slovakia	no	no
France	ns	ns	Slovenia	yes	nr*
Germany	ns	ns	Spain		yes
Greece	nr	nr	Sweden	ns	ns
Hungary	ns	ns	Switzerland	nr	nr
Iceland	/	/	Turkey	nr	nr
Ireland	ns	ns	Ukraine	nr	nr
Italy	nr	nr	United Kingdom	yes	no
Latvia	no	yes	Australia	ns	ns
Liechtenstein	nr	nr	Canada	no	yes
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	yes	no
Malta	nr	nr			

Slovenia: Obtaining father's consent is recommended by ethics committee.

128. If embryo research is lawful, until what stage of the embryo's development may it be carried out:

a) no limit? (y/n)
b) up to 14 days? (y/n)⁷
c) other? (y/n)

Country	а	b	с	Country	а	b	с
Austria	/	/	/	Netherlands	nr	nr*	nr
Belgium	nr	nr	nr	Norway	ns	ns	ns
Bulgaria	nr	nr	nr	Poland	nr	nr	nr
Cyprus	nr	nr	nr	Portugal	nr	nr	nr
Czech Rep.	nr	nr	nr	Romania	nr	nr	nr
Denmark	no	yes	no	Russia	nr	nr	nr
Estonia	no	yes	/	San Marino	nr	nr	nr
Finland	ns	ns	ns	Slovakia	no	ns	ns
France	yes*	no	/	Slovenia	no	yes	no
Germany	/	/	/	Spain	no	yes	no
Greece	nr	nr	nr	Sweden	no	yes	no
Hungary	nr	nr	nr	Switzerland	nr	nr	nr
Iceland	no	*	ns	Turkey	nr	nr	nr
Ireland	ns	ns	ns	Ukraine	nr	nr	nr
Italy	nr	nr	nr	United Kingdom	no	yes	no
Latvia	ns	ns	ns	Australia	no	yes*	no
Liechtenstein	nr	nr	nr	Canada	no	yes*	no
Lithuania	nr	/	/	New Zealand	nr	nr	nr
Luxembourg	nr	nr	nr	United States	yes*	no	no
Malta	nr	nr	nr				

⁷ This period is meant to be that of the primitive streak.
<u>France</u>: The limit imposed by French law is based on the premise that any research which may be carried out on embryos in vitro must not harm the embryos; this limit does not depend on the stage of the embryo's development.

Iceland: It is prohibited to keep an embryo outside the body for more than 14 days.

Netherlands: The future legislation would permit embryo research up to the 14th day.

<u>Australia</u>: The Human Reproductive Technology Act 1991 (WA) prohibits keeping an embryo for more than fourteen days (excluding storage periods) after the mixing of gametes.

<u>Canada</u>: As of June, 1996, the Canadian Health Minister introduced legislation that would ban research on human embryos later than fourteen days after conception.

<u>United States</u>: A NIH research panel in 1994 recommended that no research be done after the neural tube closes at four weeks past conception.

Country	Rep.	Country	Rep.
Austria	no	Netherlands	nr
Belgium	nr	Norway	no
Bulgaria	nr	Poland	no
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	no	Russia	nr
Estonia	no	San Marino	nr
Finland	ns	Slovakia	no
France	no*	Slovenia	no
Germany	no	Spain	no
Greece	nr	Sweden	ns
Hungary	nr	Switzerland	no
Iceland	no	Turkey	nr
Ireland	ns	Ukraine	nr
Italy	nr	United Kingdom	yes
Latvia	nr	Australia	no
Liechtenstein	nr	Canada	nr*
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	no
Malta	nr*		

Is it lawful to create human embryos solely for research purposes? (y/n)

129.

<u>France</u>: Article 152-8 (1) of the Public Health Code prohibits in vitro procreation of human embryos for purposes of study, research or experimentation.

<u>Malta</u>: Creation of human embryos solely for research purposes could be authorised by law but is not done in practice.

<u>Canada</u>: Recommendations state that the creation of embryos solely for purposes of scientific research should be prohibited.

130. May the human gametes employed in research be used to create embryos in vitro for the purpose of procreation? (y/n)

Country	Rep.	Country	Rep.
Austria	ns	Netherlands	no
Belgium	nr	Norway	no
Bulgaria	nr	Poland	ns
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	*	Russia	nr
Estonia	no	San Marino	nr
Finland	ns	Slovakia	no
France	nr*	Slovenia	nr
Germany	*	Spain	no
Greece	nr	Sweden	no
Hungary	nr	Switzerland	no
Iceland	no	Turkey	ns
Ireland	ns	Ukraine	nr
Italy	nr	United Kingdom	no
Latvia	nr	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	ns
Malta	nr		

<u>Denmark</u>: Such use is unlawful if the risk of transmitting a defect or a disease to offspring cannot be excluded.

<u>France</u>: It is possible for the members of a couple destined to benefit from IVF to agree concomitantly to a research protocol including gametes removed for the purposes of medically-assisted procreation.

<u>Germany</u>: According to the Protection of the Human Embryo Act whoever uses a human gamete with artificially modified genetic information for the purpose of fertilisation shall be criminally liable with up to 5 years' imprisonment.

131. Is it lawful to modify non-pathological hereditary characteristics? (y/n)

Country	Rep.	Country	Rep.
Austria	no	Netherlands	ns
Belgium	nr	Norway	no
Bulgaria	nr	Poland	no
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	no	Russia	nr
Estonia	no	San Marino	nr
Finland	ns	Slovakia	no
France	no	Slovenia	no
Germany	no*	Spain	no
Greece	nr	Sweden	no
Hungary	nr	Switzerland	no
Iceland	ns	Turkey	nr
Ireland	ns	Ukraine	nr
Italy	nr	United Kingdom	no
Latvia	nr	Australia	no
Liechtenstein	nr	Canada	no*
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	nr
Malta	no*		

<u>Germany</u>: The Protection of the Human Embryo Act prohibits artificial modification of human gametes.

Malta: Any form of modification is prohibited by analogy with abortion.

<u>Canada</u>: House Bill C-47 would prohibit altering the genetic structure of an ovum, sperm, zygote or embryo if the altered structure is capable of transmission to a subsequent generation.

132. Are the following types of genetic intervention prohibited.⁸

a) sex selection? (y/n)
b) race selection? (y/n)
c) the creation of chimera? (y/n)
d) ectogenesis (the creation of a human being in a laboratory)? (y/n)
e) genetic intervention on viable human embryos? (y/n)
f) genetic intervention on non-viable human embryos? (y/n)

g) the creation of identical twins? (y/n)

Country	a	b	c	d	e	f	g	Country	a	b	с	d	e	f	g
Austria	у	у	у	у	у	у	у	Netherds	nr*	nr	nr	nr	nr	nr	nr
Belgium	nr	nr	nr	nr	nr	nr	nr	Norway	у	у	у	у	у	у	у
Bulgaria	nr	nr	nr	nr	nr	nr	nr	Poland	у	у	у	у	у	у	у
Cyprus	nr	nr	nr	nr	nr	nr	nr	Portugal	nr	nr	nr	nr	nr	nr	nr
CzechRep.	nr	nr	nr	nr	nr	nr	nr	Romania	nr	nr	nr	nr	nr	nr	nr
Denmark	y*	у	у	у	у	ns	у	Russia	nr	nr	nr	nr	nr	nr	nr
Estonia	у	у	у	у	у	у	у	S.Marino	nr	nr	nr	nr	nr	nr	nr
Finland	ns	ns	ns	ns	ns	ns	ns	Slovakia	у	у	у	у	у	у	nr
France	y*	y*	y*	nr*	ns	ns	nr*	Slovenia	у*	у	у	у	у	у	у
Germany	у	у	у	n	у	у	у	Spain	у	у	у	у	у	n*	у
Greece	nr	nr	nr	nr	nr	nr	nr	Sweden	у	у	у	у	у	n	у
Hungary	nr	nr	nr	nr	nr	nr	nr	Switznd.	у	у	у	у	у	n	у
Iceland	у	у	у	у	у	у	у	Turkey	у	у	у	у			у
Ireland	ns	ns	ns	ns	ns	ns	ns	Ukraine	nr	nr	nr	nr	nr	nr	nr
Italy	nr	nr	nr	nr	nr	nr	nr	UKgdom	n*	*	у	у	у	n	у
Latvia	nr	nr	nr	nr	nr	nr	nr	Australia	у*	ns*	n	у	n**	ns	n***
Liechtenst.	nr	nr	nr	nr	nr	nr	nr	Canada	n*	ns	n	n	ns	ns	ns
Lithuania	nr	nr	nr	nr	nr	nr	nr	NZealnd	nr	nr	nr	nr	nr	nr	nr
Luxembrg	nr	nr	nr	nr	nr	nr	nr	UnStates	nr*	nr	nr	nr	nr	nr	nr
Malta	у*	у	у	у	у	у	у								

⁸ The following types of genetic intervention concern *non-therapeutic research*

<u>Denmark</u>: Only allowed for the purpose of excluding the transmission of a serious sex-linked disease.

<u>France</u>: Sex selection as such is prohibited by the rules on the purposes of medically-assisted procreation set out in Article L.152-2 of the Public Health Code. This prohibition does not prevent medically-assisted procreation techniques from being used with a view to averting the transmission of a particularly serious sex-linked disease to the child. In such circumstances, the choice of sex is not preferred in itself or for any reasons of convenience but simply because otherwise there would be a high risk of giving birth to a child with a serious illness.

The statutory conditions governing research which may be authorised on embryos in vitro, particularly the requirements that it must be for a medical purpose and that the embryo must not be harmed, preclude the authorisation of **research aimed at race selection, the creation of chimera, ectogenesis or the creation of identical twins.** Nevertheless, in the absence of any rules dealing specifically with such circumstances, it was decided to reply "not regulated" to the questions relating to ectogenesis and the creation of identical twins.

However, **as far as the creation of chimera and race selection is concerned**, there is reason to think, subject to the overriding discretion of the courts, that if such interventions were to be carried out notwithstanding the impossibility of their being authorised for research purposes, they would come under the rules laid down by paragraphs 1 and 2 of Article 16-4 of the Civil Code whereby no-one may harm the integrity of the human species and all eugenic practices serving to organise the selection of individuals are prohibited.

Regarding the two questions on genetic intervention on embryos, a comprehensive answer is impossible given the extremely broad nature of the concept of "genetic intervention" covering activities involving varying degrees of invasiveness. Here once again, the requirements that there should be a medical purpose to the intervention and that it should not harm the embryo are the prerequisites for any authorisation to carry out research on embryos in vitro. Embryos are also covered by paragraph 3 of Article 16-4 of the Civil Code which states that, except in the case of research for the purpose of preventing and treating genetic diseases, no changes may be made to the genetic characteristics of humans in order to modify their progeny.

Finally, as regards the **creation of identical twins**, if what is meant here is indeed the **cloning of embryos**, it should be pointed out that, though French law does not expressly prohibit cloning, it does include a whole range of safeguards which effectively render it unlawful to apply cloning techniques to humans. In this connection the following should be noted:

- the rule prohibiting any creation of embryos in vitro outside the context of medically-assisted procreation, any breach being punishable (Articles L 152-7 and L 152-8 of the Public Health Code and Articles 511-17 and 511-18 of the criminal code);

- the restrictions on the purposes of in-vitro creation of embryos in the context of medicallyassisted procreation (Articles L 152-2 and L 152-3 of the Public Health Code);

- the requirement for establishments carrying out medically-assisted procreation to obtain the authorisation of the minister for health on the advice of the National Commission for Reproductive Medicine and Biology, failure to obtain such authorisation being punishable (Articles L 152-9 and L 184-7 of the Public Health Code);

- 190 -

- the rule prohibiting eugenic practices serving to organise the selection of individuals and all changes made to the genetic characteristics of humans in order to modify their progeny, any breach being punishable (Article 16-4 of the Civil Code and 511-1 of the Criminal Code)

Malta: Any genetic intervention is presumed forbidden by analogy with abortion.

Netherlands: No statutory rules but most non-therapeutic genetic interventions are prohibited.

Slovenia: It is prohibited except if the aim is to prevent transmission of sex-related disorder.

<u>Spain</u>: All research projects on non-viable pre-embryos in vitro must be properly documented in terms of the embryological material used as well as their origin, duration of realisation and objectives. As soon as a project is finished, the results must be transmitted to the authorising body.

United Kingdom: Interventions are not prohibited but are regulated by a code of practice.

<u>Australia</u>: * Sex selection is permitted to screen for sex-linked genetic diseases [Infertility (Medical Procedures) Act 1984].

** Embryo experimentation which would harm the embryo is prohibited (Victoria).

*** Although the creation of identical twins is not specified, cloning is prohibited.

Canada: House Bill C-47 would prohibit sex selection and the creation of animal-human hybrids.

United States: Illinois and Pennsylvania have statutes prohibiting sex selection.

- 133. Is there either legislation or codes of practice governing the use of tissues obtained from:
 - a) embryo in vivo? (y/n)
 b) embryo in vitro? (y/n)
 c) foetal in vivo? (y/n)
 d) foetal in vitro? (y/n)
- [134. If so, what is the legal nature of either legislation or codes of practice : a) on embryo tissue?

b) on foetal tissue?]

Country	133 a	b	c	d	Country	133 a	b	c	d
Austria	/*	/	/*	/	Netherlands	nr	nr	nr	nr
Belgium	n	n	n	n	Norway	*		*	
Bulgaria	nr	nr	nr	nr	Poland	ns	ns	ns	ns
Cyprus	nr	nr	nr	nr	Portugal	nr	nr	nr	nr
Czech Rep.	nr	nr	nr	nr	Romania	nr	nr	nr	nr
Denmark	у	у	у	у	Russia	nr	nr	nr	nr
Estonia	n	n	n	n	San Marino	nr	nr	nr	nr
Finland	ns	ns	ns	ns	Slovakia	у*	у*	у*	у*
France	у*	у	у	у	Slovenia	n	n	n*	у*
Germany	у*	у*	y**	y**	Spain	у	у	у	у
Greece	nr	nr	nr	nr	Sweden	у	n	у	n
Hungary	nr	nr	nr	nr	Switzerland	nr	nr	nr	nr
Iceland	ns	ns	ns	ns	Turkey	nr	nr	nr	nr
Ireland	n	n*	n*	n*	Ukraine	nr	nr	nr	nr
Italy	nr	nr	nr	nr	United Kingdom	у	у	у	у
Latvia	nr	nr	nr	nr	Australia	ns	ns	ns	ns
Liechtenstein	nr	nr	nr	nr	Canada	ns	ns	ns	ns
Lithuania	nr	nr	nr	nr	New Zealand	ns	ns	ns	ns
Luxembourg	nr	nr	nr	nr	United States	у	у	у	у
Malta	nr	nr	nr	nr					

- 192 -

Austria: Not to be used for cosmetics (law BGBC 1996/167).

Denmark: There is a law on inspection of the dead, post mortem examinations and transplantation.

<u>France</u>: Any interpretation of the detailed implications of this and the two following questions (No.135 and 136) is somewhat speculative in view of the fact that it is not specified whether the terms in vivo and in vitro refer to the origins of the embryonic tissue involved or the use to which it may be put.

From the point of view of French law, the use of tissue from embryos or foetuses is governed by rules deriving from the application of the principle of non-commercialisation of the human body and its parts and products, laid down in Article 16-1 of the Civil Code, as well as in certain of the criminal provisions contained in Articles 511-4, 511-15 and 511-17 of the Criminal Code.

<u>Germany</u>: * The Protection of the human Embryo Act and Model Professional Code. ** Professional regulations.

Ireland: This prohibition could be a constitutional issue.

<u>Norway</u>: The government presented a parliamentary report dealing with foetal tissues in December 1995.

Slovakia: Law 277/94.

<u>Slovenia</u>: The draft law on transplantation allows the use of tissues from aborted foetuses for transplantation in exceptional cases, subject to the approval by the National Medical Ethics Committee. The transplantation interest is not allowed to influence, in any way, the decision for, timing, methods or other circumstances of abortion. The medical team which is to perform transplantation and the physician of the patient receiving the tissue may not be connected with the team or doctor performing the abortion.

135.

Is the use of embryo tissue lawful:

a) in vivo? (y/n) b) in vitro? (y/n)

Country	a	b	Country	a	b
Austria	no	no	Netherlands	nr	nr
Belgium	nr	nr	Norway	*	
Bulgaria	nr	nr	Poland	no	no
Cyprus	nr	nr	Portugal	nr	nr
Czech Rep.	nr	nr	Romania	nr	nr
Denmark	yes	yes	Russia	nr	nr
Estonia	no	no	San Marino	nr	nr
Finland	ns	ns	Slovakia	yes	yes
France	yes*	yes*	Slovenia	yes*	yes*
Germany	*	*	Spain	yes	yes
Greece	nr	nr	Sweden	nr	nr
Hungary	nr	nr	Switzerland	no	no
Iceland	ns	ns	Turkey	nr	nr
Ireland	*	*	Ukraine	nr	nr
Italy	nr	nr	United Kingdom	yes	yes
Latvia	nr	nr	Australia		
Liechtenstein	nr	nr	Canada	nr	nr
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	у*	у*
Malta	nr*	nr*			

<u>France</u>: There are no specific rules on this question in the bioethics law of 29 July 1994. It should be said that, in an opinion of 22 May 1984 on the removal of tissue, embryos and dead human foetuses for therapeutic, diagnostic and scientific use, the French National Advisory Committee on Ethics concluded that removal should be allowed for diagnostic purposes (investigating the causes of a miscarriage, confirming the results of tests justifying a therapeutic abortion) or, in exceptional cases for therapeutic purposes (for example the treatment of immunodeficient children by transplanting embryo tissue).

Germany: The question cannot be answered in such general terms.

Ireland: Use of tissues other than the placenta could raise constitutional problems.

<u>Malta</u>: Use of unviable embryonic tissues could be permitted by law but is not practised for the time being.

<u>Norway</u>: The government presented a parliamentary report dealing with foetal tissues in December 1995.

Slovenia: Both subject to approval by the National Medical Ethics Committee.

United States: Prohibitions at the State level usually refer to foetal tissue and not embryonic tissue.

136.

Is the use of foetal tissue lawful:

a) in vivo? (y/n) b) in vitro? (y/n)

Country	а	b	Country	a	b
Austria	no	no	Netherlands	nr	nr
Belgium	nr	nr	Norway	*	
Bulgaria	nr	nr	Poland	no	no
Cyprus	nr	nr	Portugal	nr	nr
Czech Rep.	nr	nr	Romania	nr	nr
Denmark	no	no	Russia	nr	nr
Estonia	no	no	San Marino	nr	nr
Finland	ns	ns	Slovakia	yes	yes
France	yes*	yes*	Slovenia	yes*	yes*
Germany	*	*	Spain	yes	yes
Greece	nr	nr	Sweden	yes	yes
Hungary	nr	nr	Switzerland	no	no
Iceland	ns	ns	Turkey	nr	nr
Ireland	*		Ukraine	nr	nr
Italy	nr	nr	United Kingdom	yes	yes
Latvia	nr	nr	Australia	yes	ns
Liechtenstein	nr	nr	Canada	nr	nr
Lithuania	nr	nr	New Zealand	nr	nr
Luxembourg	nr	nr	United States	yes*	yes*
Malta	nr*	nr			

<u>France</u>: There are no specific rules on this question in the bioethics law of 29 July 1994. It should be said that, in an opinion of 22 May 1984 on the removal of tissue, embryos and dead human foetuses for therapeutic, diagnostic and scientific use, the French National Advisory Committee on Ethics concluded that removal should be allowed for diagnostic purposes (investigating the causes of a miscarriage, confirming the results of tests justifying a therapeutic abortion) or, in exceptional cases for therapeutic purposes (for example the treatment of immunodeficient children by transplanting embryo tissue).

Germany: The question cannot be answered in such general terms.

Ireland: Use of tissues other than the placenta could raise constitutional problems.

Malta: Not practised, but use of tissues from dead foetuses might be permitted by law.

<u>Norway</u>: The government presented a parliamentary report dealing with foetal tissues in December 1995.

Slovenia: Both subject to approval by the National Medical Ethics Committee.

<u>United States</u>: Foetal tissue transplantation research may be conducted for "therapeutic purposes." Nineteen States prohibit non-therapeutic research on living foetuses and the rest follow federal regulations that prohibit research on a live nonviable foetus ex utero unless the treatment is therapeutic.

137. Is special authorisation necessary for the use of embryo or foetal tissue? (y/n)

Country	Rep.	Country	Rep.
Austria	/	Netherlands	nr
Belgium	nr	Norway	nr
Bulgaria	nr	Poland	nr
Cyprus	nr	Portugal	nr
Czech Rep.	nr	Romania	nr
Denmark	no	Russia	nr
Estonia	yes	San Marino	nr
Finland	ns	Slovakia	yes
France	no	Slovenia	yes
Germany	yes*	Spain	yes
Greece	nr	Sweden	no
Hungary	nr	Switzerland	ns
Iceland	ns	Turkey	nr
Ireland	nr	Ukraine	nr
Italy	nr	United Kingdom	yes
Latvia	nr	Australia	yes
Liechtenstein	nr	Canada	nr
Lithuania	nr	New Zealand	nr
Luxembourg	nr	United States	yes*
Malta	nr		

<u>Germany</u>: It should be submitted for assessment to the Ethics Committee, which is to satisfy itself that the proposed research meets the highest scientific standards, that the expected results cannot be obtained by any other means, and that the researcher has been suitably trained and is provided with suitable scientific and technical equipment.

<u>United States</u>: Federal regulations apply only to researchers who receive federal funds or who are affiliated with an institution that has signed an agreement with the Department of Health and Human Services.

- 199 -

- 138. Is termination of pregnancy forbidden by law? (y/n)
- 139. If no, is termination of pregnancy possible for reasons of embryo or foetal malformation or handicap? (y/n)

Country	138	139	Country	138	139
Austria	yes*	*	Netherlands	no	yes
Belgium	no	yes	Norway	no	yes
Bulgaria	ns	ns	Poland	no	ns
Cyprus	no	yes	Portugal	no	yes*
Czech Rep.	no*	ns	Romania	ns	ns
Denmark	no	yes	Russia	ns	ns
Estonia	yes	yes	San Marino	ns	ns
Finland	no	ns	Slovakia	no	yes
France	no	yes*	Slovenia	no	yes
Germany	*	**	Spain	no	yes
Greece	no	yes	Sweden	no	ns
Hungary	ns	ns	Switzerland	no	ns
Iceland	no	yes	Turkey	no	ns
Ireland	*		Ukraine	ns	ns
Italy	no	ns	United Kingdom	no	ns
Latvia	no	yes	Australia	no	ns
Liechtenstein	ns	ns	Canada	no	ns
Lithuania	no	yes	New Zealand	no	yes
Luxembourg	no	yes	United States	no	yes*
Malta	yes	ns			

Austria: Abortion is forbidden by law unless:

1) it is carried out by a doctor during the first 3 months of pregnancy and after consultation of a doctor by the woman, or

2) it is necessary to avert serious and otherwise inevitable danger to life, or to avert serious damage to the physical or mental health of the pregnant woman, or if there is a serious danger that the child will be seriously handicapped, mentally or physically, or if the mother was a minor at the time she fell pregnant and if, in all these cases, the abortion is carried out by a doctor.

<u>Czech Republic</u>: Abortion may not be practised on non-residents. The penalty for the doctor is loss of licence.

<u>France</u>: Pregnancies may be terminated for reasons linked to the health of the child only if there is a strong probability, certified by two doctors, that the child will be born with a particularly serious ailment recognised as incurable at the time of diagnosis.

<u>Germany</u>: * On principle terminations of pregnancy attract criminal liability pursuant to the Criminal Code in respect of all participants. There are, however, exceptions to this. The most important exceptions are as follows :

Commission of the offence of terminating a pregnancy is ruled out under certain further conditions if, pursuant to the Pregnancy Conflict Act, the pregnant woman has been counselled and not more than 12 weeks have elapsed since conception.

The unlawfulness of terminating a pregnancy is ruled out under certain further conditions:

- in the case of the so-called medical indication, ie. when termination of pregnancy is necessary taking into account present and future circumstances in the life of the pregnant woman, in order to avert a danger to the life, or the risk of causing serious impairment to the physical or mental health, of the pregnant woman, without reference to any time limitation,

- in the case of the so-called criminological indication, ie. when there are strong grounds for supposing that pregnancy is due to a sexual offence (sexual abuse of children, rape, sexual coercion or sexual abuse of persons incapable of offering resistance) until 12 weeks after conception.

** Since 1 October 1995 the relevant provisions of the Criminal Code no longer make provision for a so-called embryopathic indication - according to which continuation of a pregnancy cannot reasonably be expected on the ground that serious impairment to the child's health is to be expected. Under the new law, however, a medical indication (see answer to question 138) may exist in such cases if, taking into account present and future circumstances in the life of the pregnant woman, a serious danger is posed to the physical or mental health of the mother.

<u>Ireland</u>: The Constitution secures equal rights to the mother and the child. The Supreme Court has interpreted this provision as permitting termination of pregnancy if its continuation endangers the mother's life. Specific legislation is under consideration.

<u>Portugal</u>: Only during the first 24 weeks of pregnancy, where there are serious reasons to believe that the embryo or the foetus will suffer of a incurable serious disease or congenital malformation. In the case of non viable foetuses, abortion can be made at any time.

United States: In most American States, this is not prohibited.

140. May the decision to terminate a pregnancy and the conditions of termination be influenced by the subsequent use of the embryo or foetus? (y/n)

Country	Rep.	Country	Rep.
Austria	no	Netherlands	no
Belgium	ns	Norway	no
Bulgaria	ns	Poland	ns
Cyprus	ns	Portugal	no
Czech Rep.	ns	Romania	ns
Denmark	no	Russia	ns
Estonia	no	San Marino	ns
Finland	no	Slovakia	no
France	no	Slovenia	no
Germany	no	Spain	no
Greece	ns	Sweden	no
Hungary	ns	Switzerland	ns
Iceland	no	Turkey	ns
Ireland	ns	Ukraine	ns
Italy	ns	United Kingdom	no
Latvia	no	Australia	no*
Liechtenstein	ns	Canada	nr
Lithuania	nr	New Zealand	nr
Luxembourg	no	United States	no*
Malta	ns		

<u>United States</u>: Department of Health and Human Services specifies that no "inducements" may be offered to the woman to influence her decision to terminate her pregnancy.

141.	Is there a requirement for the medical team terminating the pregnancy? (y/n)
------	--

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	ns
Belgium	ns	Norway	no
Bulgaria	ns	Poland	ns
Cyprus	ns	Portugal	ns
Czech Rep.	ns	Romania	ns
Denmark	no	Russia	ns
Estonia	yes	San Marino	ns
Finland	yes	Slovakia	yes
France	yes	Slovenia	yes
Germany	*	Spain	yes
Greece	yes	Sweden	yes
Hungary	ns	Switzerland	ns
Iceland	ns	Turkey	ns
Ireland	ns	Ukraine	ns
Italy	ns	United Kingdom	yes
Latvia	yes	Australia	ns
Liechtenstein	ns	Canada	ns
Lithuania	yes	New Zealand	ns
Luxembourg	ns	United States	no
Malta	ns		

Commission of the offence of terminating a pregnancy is ruled out under certain further conditions if, pursuant to the Pregnancy Conflict Act, the pregnant woman has been counselled and not more than 12 weeks have elapsed since conception.

The unlawfulness of terminating a pregnancy is ruled out under certain further conditions:

- in the case of the so-called medical indication, ie. when termination of pregnancy is necessary taking into account present and future circumstances in the life of the pregnant woman, in order to avert a danger to the life, or the risk of causing serious impairment to the physical or mental health, of the pregnant woman, without reference to any time limitation,

- in the case of the so-called criminological indication, ie. when there are strong grounds for supposing that pregnancy is due to a sexual offence (sexual abuse of children, rape, sexual coercion or sexual abuse of persons incapable of offering resistance) until 12 weeks after conception.

A medical practitioner terminating a pregnancy must, moreover, discharge the following duties in order to avoid criminal liability:

- He must give the woman an opportunity to explain why she wants to terminate her pregnancy.

- He must give the pregnant woman medical advice on the significance of the operation, in particular as to its course, the consequences, risks and possible physical and mental effects.

- In counselling cases and in cases of criminological indication he must satisfy himself as to the length of the pregnancy by medical examination (eg. by ultrasound).

Where a medical practitioner gives a pregnant woman advice in the context of the counselling provisions the same doctor is not allowed to terminate her pregnancy himself.

- 206 -

142.

Country	Rep.	Country	Rep.
Austria	ns	Netherlands	ns
Belgium	ns	Norway	no
Bulgaria	ns	Poland	no
Cyprus	ns	Portugal	ns
Czech Rep.	ns	Romania	ns
Denmark	no	Russia	ns
Estonia	no	San Marino	ns
Finland	ns	Slovakia	no
France	ns	Slovenia	no
Germany	no	Spain	no
Greece	nr	Sweden	nr
Hungary	ns	Switzerland	ns
Iceland	no	Turkey	ns
Ireland	ns	Ukraine	ns
Italy	ns	United Kingdom	yes
Latvia	no	Australia	ns
Liechtenstein	nr	Canada	ns
Lithuania	nr	New Zealand	ns
Luxembourg	ns	United States	ns
Malta	nr*		

Malta: Could be permitted by law.

143. Is the pregnant woman given information about the removal, its aim and the risks involved? (y/n)

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	ns
Belgium	ns	Norway	yes
Bulgaria	ns	Poland	yes
Cyprus	ns	Portugal	ns
Czech Rep.	ns	Romania	ns
Denmark	yes	Russia	ns
Estonia	yes	San Marino	ns
Finland	ns	Slovakia	*
France	ns	Slovenia	yes
Germany	yes	Spain	yes
Greece	ns	Sweden	yes
Hungary	ns	Switzerland	yes
Iceland	yes	Turkey	yes
Ireland	ns	Ukraine	ns
Italy	ns	United Kingdom	yes
Latvia	yes	Australia	yes*
Liechtenstein	ns	Canada	yes*
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	ns
Malta	nr		

Slovakia: In reasonable cases.

<u>Australia</u>: In Victoria, gamete donors must receive counselling. One can presume this requirement can be applied to pregnant women who elect to have embryonic or foetal tissue removed.

Canada: House Bill C-47 requires consent of a woman whose embryo is removed.

Is the woman's consent necessary for the removal of embryo material? (y/n) 144.

Country	Rep.	Country	Rep.
Austria	yes	Netherlands	ns
Belgium	ns	Norway	yes
Bulgaria	ns	Poland	yes
Cyprus	ns	Portugal	nr
Czech Rep.	ns	Romania	ns
Denmark	yes	Russia	ns
Estonia	yes	San Marino	ns
Finland	ns	Slovakia	no
France	ns	Slovenia	yes
Germany	yes	Spain	yes
Greece	ns	Sweden	yes
Hungary	ns	Switzerland	yes
Iceland	yes	Turkey	yes
Ireland	ns	Ukraine	ns
Italy	ns	United Kingdom	yes
Latvia	yes	Australia	yes
Liechtenstein	ns	Canada	yes*
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	yes
Malta	nr		

Canada: In the House Bill C-47.

Country	Rep.	Country	Rep.
Austria	ns	Netherlands	no
Belgium	ns	Norway	no
Bulgaria	ns	Poland	no
Cyprus	ns	Portugal	nr
Czech Rep.	ns	Romania	ns
Denmark	no	Russia	ns
Estonia	no	San Marino	ns
Finland	ns	Slovakia	no
France	no*	Slovenia	no*
Germany	no	Spain	no
Greece	no	Sweden	no
Hungary	ns	Switzerland	no*
Iceland	no	Turkey	no
Ireland	ns	Ukraine	ns
Italy	ns*	United Kingdom	no
Latvia	no	Australia	no*
Liechtenstein	ns	Canada	no*
Lithuania	nr	New Zealand	ns
Luxembourg	nr	United States	no
Malta	nr		

145. May embryo tissue intended for therapeutic use be sold? (y/n)

<u>France</u>: Under Article 16-1 of the Civil Code, the human body and its parts and products cannot be commercialised. Under Article 511-4 of the Criminal Code involvement in the procurement of human tissue, cells or products in exchange for payment is punishable by imprisonment and fines. Furthermore, the creation and use of human embryos for commercial gain is prohibited under Article 511-17 of the Criminal Code and punishable by imprisonment and fines.

<u>Italy</u>: Article 3 (3) of the bill prohibits all forms of commercial or industrial use of embryonic and foetal tissues. Creation and use of embryos for commercial purposes is prohibited by law and punishable by imprisonment or a fine.

<u>Slovenia</u>: There is one case of placental tissue being collected, on a non-profit basis, for the production of a medicinal substance, with the authorization of the National Medical Ethics Committee.

<u>Switzerland</u>: Sale is prohibited by the Constitution. It is a punishable offence gainfully to dispose of or acquire human germ material or products derived from embryos or foetuses.

Australia: This is prohibited in both Western Australia and Victoria.

Canada: House Bill C-47 would prohibit such a commercial exchange.

III - CLONING

146. Is it legally forbidden to create human clones (embryos with the same karyotypeas another embryo or a living or dead person)?

Country	Resp.	Country	Resp.
Albania	-	Malta	nr
Andorra		Moldova	
Austria	yes*	Netherlands	nr*
Belgium	nr	Norway	no
Bulgaria	nr	Poland	
Croatia	no*	Portugal	nr*
Cyprus		Romania	
Czech Rep.		Russia	
Denmark	yes*	San Marino	nr
Estonia	nr*	Slovakia	yes
Finland	nr*	Slovenia	yes*
France	non*	Spain	yes*
Germany	yes*	Sweden	yes*
Greece	nr*	Switzerland	
Hungary		the FYROM ¹	
Iceland	yes*	Turkey	yes
Ireland	no*	Ukraine	no*
Italy		United Kingdom	yes*
Latvia	nr	Australia	
Liechtenstein		Canada	nr*
Lithuania	nr*	New Zealand	
Luxembourg	nr*	United States	

¹ the former Yugoslav Republic of Macedonia

Austria: Paragraph. 9 No.1 "Fortpflanzungsmedizingesetz - FMedG".

<u>Denmark</u>: According to the Act on artificial procreation in connection with medical treatment, diagnostics and research, etc. it is forbidden to create human clones both in research and treatment.

<u>Croatia</u>: A new law on medically-assisted procreation is in preparation and probably some provisions will be on human cloning.

Estonia: There is not yet official legislation on artificial procreation and embryo protection but a draft law is in parliamentary commission and will be discussed in the near future. The prohibition of cloning is stated in Article 35 (2) of the draft law. ("Is forbidden: (....) the creation of fertilized identical embryos with the same genetic information by changing of embryos nucleus with an other nucleus from an embryo, foetus, living or dead human somatic cells.")

<u>Finland</u>: Not yet. It will be included in the law on medical research. The draft law should be given to Parliament during this year. The prohibition will be general.

<u>France</u>: French legislation does not expressly ban the use of cloning techniques on human beings. This lack of an explicit prohibition cannot however be interpreted either as indicating the existence of a legal vacuum, or as implying that cloning is authorised. The report dated 22 April 1997 on this subject, prepared by the National Advisory Committee on ethics relating to life sciences and health (*Comité consultatif national d'éthique pour les sciences de la vie et de la santé*), came to the conclusion that, in order to achieve a result consistent with its own condemnation of human cloning in ethical terms, it was not necessary to amend the provisions of the French Civil Code or Public Health Code currently in force.

This standpoint may be justified by taking the following factors into account:

1) The hypothetical creation of creating human clones for research purposes or as a source of biological material to be used for therapeutic purposes: This would be deemed unlawful under the provisions of a general nature embodied in Articles L 152-3 and L 152-8 of the Public Health Code. The principles enunciated by these Articles prohibit the creation of human embryos *in vitro* for purposes other than medically assisted procreation (abovementioned Article L 152-3) and, more particularly, their creation for purposes of study, research or experimentation (Article L 152-8). It should be noted that the lack of any definition of the term embryo in French legislation means that it can encompass the process of development resulting from a cloning operation which could potentially lead to childbirth if the embryo were implanted.

2) Possibility of using cloning techniques in the field of medically assisted procreation (in response to a problem of total sterility or a risk of transmitting a hereditary disease to the future child): In French law, without prejudice to the independent rulings of by the law-courts, the following provisions render the use of such applications unlawful:

- Article 16 of the Civil Code which states that the law ensures the primacy of the human being, prohibits any infringement of human dignity and guarantees the respect of the human person from the inception of life. Emphasis should be placed on the constitutional weight of the principle of safeguarding the dignity of the human being, following the decision relating to the laws on bioethics handed down on 27 July 1994 by the French Constitutional Council. It may plausibly be argued that the ban on infringements of human dignity proclaimed by French legislation is applicable even if the "person" concerned, at the time of the cloning operation, is a potential person

to be born as a result of implanting the embryo obtained in this way. The opinion recently expressed by the French National Ethics Committee confirms the validity of this interpretation, namely that, whatever the purpose pursued and whatever the technique employed, all forms of cloning whereby an asexually reproduced organism is introduced into the human species, constitute a radical infringement of human dignity.

- Article 16-4, section 3 of the Civil Code, the first paragraph of which states that no-one shall impair the integrity of the human species, while paragraph 3 of the same Article prohibits any transformation of genetic characteristics with a view to altering a person's offspring. The prohibition embodied in these provisions nevertheless seems to be limited to certain cloning techniques (transfer of the nucleus of an embryo or somatic cell, but not the artificial division of an embryo), or even certain objectives of the cloning process.

- Articles L 152-2 and L 152-3 of the Public Health Code: the terms of these provisions, which restrict the possibilities of *in vitro* fertilisation of an embryo to the context and for the purposes of medically assisted procreation, also have implications for the technique of asexual reproduction made possible by cloning. Since the provisions contained in the regulations for applying the Public Health Code mention only those techniques which enable an embryo to be constituted by sexual reproduction, it follows that the French legislature intended to authorise only those forms of assistance to childbearing which entail the induced fusion of the gametes of a couple desiring parenthood. Moreover, the restricted character of the medically assisted procreation activities authorised by the national legislature is reinforced in practice by virtue of the French system which requires all centres practising these activities to obtain the authorisation of the Minister responsible for health affairs, after consultation of the National Commission for Reproductive Medicine and Biology, failing which a centre may incur criminal sanctions. Issue of the relevant authorisation depends on the biological nature of the techniques for assisting childbirth which are practised in the centre concerned.

<u>Germany</u>: German Act on the protection of Embryos (Gesetz zum Schutz von Embryonen - Embryonenschutzgesetz - ESchG) dated december 13, 1990, which entered into force on January 1, 1991.

<u>Greece</u>: However, cloning would be unlawful under general legislation and the constitution.

Iceland: Law on artificial procreation No. 55, 29 May 1996, Article 12.

<u>Ireland</u>: Ireland does have a written constitution under which such research would be precluded. Cloning would obviously be identified as research and hence while there is no specific legislation relating to cloning the protection of the individual from the moment of inception would preclude it. Finally the Medical Council Guidelines which regulate the activity of the Medical profession would not permit cloning in any of the circumstances identified.

Lithuania: Two law projects will deal with the human cloning : one on family health, one on biomedical research.

<u>Luxembourg</u>: Not yet, but the Health Commission of the Parliament has already taken the human cloning question into consideration.

<u>Netherlands</u>: Legislation is in preparation. The prohibition will be general: any technique to create human clones will be forbidden. It will not be allowed for any purpose. A bill will be sent to

Parliament at the beginning of 1998.

Norway: A bill was sent to the Parliament in May 1997.

<u>Portugal</u>: Opinion given by the National Committee of Ethics on law proposed by the Ministry of Health. The National Parliament has also taken advice from the National Committee of Ethics concerning human cloning.

<u>Slovenia</u>: The Bill on treatment of infertility and fertilisation with biomedical assistance (1997) contains a provision explicitly prohibiting "the creation of genetically identical embryos or embryos genetically identical with another living or dead human being".

Spain: Law on donation and use of human embryos and foetuses, including derived tissues, cells and organs. (Law No. 42/1988).

"The following are serious infractions :

k) Creating identical human through cloning or other procedures for the purpose of race selection.

l) Creating humans through cloning (or some other variant) or some other procedure capable of developing identical humans."

The ban appears in the same terms in Law No. 35/1988 on medically assisted procreation techniques and in the 1995 Criminal Code which generally punish genetic engineering which are not for diagnostic or therapeutic purposes, in particular the creation of identical human beings through cloning or other techniques.

<u>Sweden</u>: Implied prohibition (Act N° 115, 14 March 1991): "If a fertilised ovum has been a subject of experimentation for purposes of research or treatment, it may not be implanted in a woman's body. The same applies if the ovum, before fertilisation, or the sperm cells used for fertilisation have been a subject of experimentation".

<u>Ukraine</u>: A question concerning human cloning never appears among specialist of that field.

<u>United Kingdom</u>: No embryos may be created without a licence.

<u>Canada</u>: The proposed "Human Reproductive and Genetic Technologies Act (Bill C-47) which was introduced in Parliament in June 1996 and has advanced to the stage of third reading at the time Parliament prorogued in April 1997. It is the intention of the Health Department to reintroduce similar legislation in the next session of Parliament, but this is dependent on the wishes of the next Minister of Health, following the federal election on June 2nd.

Bill C-47 included a specific provision which was intended to prohibit human cloning. "Paragraph 4 (1) No person shall knowingly

(a) manipulate a human cell, zygote or embryo for the purpose of producing a zygote or embryo that contains the same genetic information as a living or deceased human being or a zygote, embryo or foetus, or implant in a woman a zygote or embryo so produced;"

This prohibition was intended to be general, that is, to prohibit all forms of human cloning.

147. If so, is the prohibition:

- general (i.e. for any purpose and through any technique)? only for some purposes (cf. question N° 148)? only for some techniques (cf. question N° 149)? a.
- b.
- c.

Country	а	b	c	Country	a	b	с
Albania				Malta	nr	nr	nr
Andorra				Moldova			
Austria	yes	no	no	Netherlands	nr	nr	nr
Belgium	nr	nr	nr	Norway	yes		
Bulgaria	nr	nr	nr	Poland			
Croatia	nr	nr	nr	Portugal	nr	nr	nr
Cyprus				Romania			
Czech Rep.				Russia			
Denmark	у	n	n	San Marino	nr	nr	nr
Estonia	nr	nr	nr	Slovakia	yes	no	yes
Finland	nr	nr	nr	Slovenia	yes	no	no
France	nr	nr	nr	Spain	yes	no	no
Germany	у	n	n	Sweden	у	n	n
Greece	nr	nr	nr	Switzerland			
Hungary				the FYROM ¹			
Iceland	у	n	n	Turkey	у	n	n
Ireland	nr	nr	nr	Ukraine	nr	nr	nr
Italy				United Kingdom	n	n	n
Latvia	nr	nr	nr	Australia			
Liechtenstein				Canada	nr	nr	nr
Lithuania	nr	nr	nr	New Zealand			
Luxembourg	nr	nr	nr	United States			

¹ the former Yugoslav Republic of Macedonia

148. If the prohibition is limited to some purposes, is it allowed to create human clones:

- a. for research purposes?
- b. as a possible source of biological material (particularly tissue) which could be used for therapeutic purposes?
- c. with a view to avoiding the transmission of a hereditary disease to the future child (for example a mitochondrial disease)?
- d. with a view to solving problems of absolute sterility (cloning a sterile person by transferring the nucleus of a somatic cell)?
- e. with a view to solve infertility problems and multiply the chances for pregnancy (artificial creation of twins)?
- f. other purposes?

Country	a	b	c	d	e	f	Country	a	b	c	d	e	f
Albania							Malta	nr	nr	nr	nr	nr	nr
Andorra							Moldova						
Austria	/	/	/	/	/	/	Netherlands	nr	nr	nr	nr	nr	nr
Belgium	nr	nr	nr	nr	nr	nr	Norway	nr	nr	nr	nr	nr	nr
Bulgaria	nr	nr	nr	nr	nr	nr	Poland						
Croatia	nr	nr	nr	nr	nr	nr	Portugal	nr	nr	nr	nr	nr	nr
Cyprus							Romania						
Czech Rep.							Russia						
Denmark	/	/	/	/	/	/	San Marino	nr*	nr	nr	nr	nr	nr
Estonia	nr	nr	nr	nr	nr	nr	Slovakia	no	no	no	no	no	no
Finland	nr	nr	nr	nr	nr	nr	Slovenia	/	/	/	/	/	/
France	nr	nr	nr	nr	nr	nr	Spain	/	/	/	/	/	/
Germany	/	/	/	/	/	/	Sweden	/	/	/	/	/	/
Greece	nr	nr	nr	nr	nr	nr	Switzerland						
Hungary							the FYROM ¹						
Iceland	/	/	/	/	/	/	Turkey	/	/	/	/	/	/
Ireland	nr	nr	nr	nr	nr	nr	Ukraine	nr	nr	nr	nr	nr	nr
Italy							United Kingdom	n*	n*	*	*	n*	n
Latvia	nr	nr	nr	nr	nr	nr	Australia						
Liechtenstein							Canada	nr	nr	nr	nr	nr	nr
Lithuania	nr	nr	nr	nr	nr	nr	New Zealand						
Luxembourg	nr	nr	nr	nr	nr	nr	United States						

¹ the former Yugoslav Republic of Macedonia

<u>San Marino</u>: Theoretically this could happen for research purpose but only after explicit resolution by the Congress State (Government).

<u>United Kingdom</u>: a) In practical terms, the answer is no. Embryos may only be created for research purposes if a licence is granted by the Human Fertilisation and Embryology Authority, who would not issue a licence for this purpose.

b) The Human Fertilisation and Embryology Act does not allow embryos to be created for such a purpose.

c) This cannot be answered in a yes/no fashion. The Human Fertilisation and Embryology Act 1990 specifically forbids cloning by replacement of nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo. The production of an embryo by a different cloning method would be subject to licensing by the Human Fertilisation and Embryology Authority.

d) This cannot be answered in a yes/no fashion. The Human Fertilisation and Embryology Act 1990 specifically forbids cloning by replacement of nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo. The production of an embryo by a different cloning method would be subject to licensing by the Human Fertilisation and Embryology Authority.

e) The Human Fertilisation and Embryology Authority has announced that it would not license cloning embryo splitting to create twins.

- 221 -

149. If the prohibition only refers to some techniques, are the following techniques prohibited:

- a. artificial embryo split?
- b. transfer of the nucleus of an embryonic cell?
- c. transfer of the nucleus of a somatic cell?

Country	а	b	с	Country	a	b	с
Albania				Malta	nr	nr	nr
Andorra				Moldova			
Austria	/	/	/	Netherlands	nr	nr	nr
Belgium	nr	nr	nr	Norway	nr	nr	nr
Bulgaria	nr	nr	nr	Poland			
Croatia	nr	nr	nr	Portugal	nr	nr	nr
Cyprus				Romania			
Czech Rep.				Russia			
Denmark	/	/	/	San Marino	nr	nr	nr
Estonia	nr	nr	nr	Slovakia	yes	yes	yes
Finland	nr	nr	nr	Slovenia	yes	yes	yes
France	nr	nr	nr	Spain	/	/	/
Germany	/	/	/	Sweden	/	/	/
Greece	nr	nr	nr	Switzerland			
Hungary				the FYROM ¹			
Iceland	/	/	/	Turkey	у	у	у
Ireland	nr	nr	nr	Ukraine	nr	nr	nr
Italy				United Kingdom	у*	у	у*
Latvia	nr	nr	nr	Australia			
Liechtenstein				Canada	nr	nr	nr
Lithuania	nr	nr	nr	New Zealand			
Luxembourg	nr	nr	nr	United States			

¹ the former Yugoslav Republic of Macedonia

<u>United Kingdom</u>: a) The Human Fertilisation and Embryology Authority has announced that such techniques will not be licensed.

c) The Human Fertilisation and Embryology Act 1990 specifically forbids cloning by replacement of nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo. The production of an embryo by a different cloning method would be subject to licensing by the Human Fertilisation and Embryology Authority.