Appendix: Surveillance 2004 I.F.F.S. questionnaire for countries with statutory, voluntary, or no guidelines for assisted reproductive technology (ART)

(Please answer this questionnaire as to the status on April 30, 2003)

Respondent:
For the sovereign country of:
Number of centers in your country:
Date of response:

Note: Each respondent is requested to fill out either Section I, or II, or III, and Sections IV, V, and VI. If your country has statutory provisions, laws, or official regulations for ART, use Section I. If your country operates under guidelines by a voluntary, religious, or other organization, use Section II. If your country has neither statutory regulations nor guidelines, use Section III. You may find that in your country some ART items are covered by statute and other items are covered by guidelines or not covered at all, i.e., there may be regulations that cover the embryology or endocrinology laboratories, but not other aspects of the program. Thus, you have a mixed situation. In this case, please make a mixed response, i.e., use Section I for statutory items, Section II for guideline items, and Section III for no coverage items.

You must answer according to the situation at the time of the answer. If there is in your country a project of law or of modification of the regulations being currently discussed, fill a last page with explanations.

If there is no change from the situation of 2000 (Surveillance 2001), answer as idem 00.

Please return this questionnaire by May 30, 2003, to: Dr Henk J Out, Organon International, KA4006, PO Box 20, 5340 BH Oss, The Netherlands, E-mail: henkjian.out@organon.com.

SECTION I—STATUTORY IVF ONLY

1. Are there statutes, i.e., law? (national or other political sub-division) governing the use of ART? (Yes/No) If yes, please supply a copy of the statute or indicate where one may be obtained. If yes, is there a licensing body? (Yes/No) If yes, what is the composition? If yes, what are the criteria for a license? If there is a law, how is clinical surveillance carried out? (Circle correct answer or answers.) [a] Periodic report, [b] On-site inspection, [c] Other. If other, please describe. Are penalties designated for violation of statutes with regard to clinical practice? (Yes/No) If yes, what are they? If there is a law, how is embryological laboratory surveillance carried out? (Circle correct answer or answers.) [a] Periodic report, [b] On-site inspection, [c] Other. If other, please describe. Are penalties designated for violation of statutes with regard to laboratory procedures? (Yes/No) If yes, what are they? If no, please proceed to Section II or III as appropriate. If yes, complete the additional questions in Section I to which the statute applies.

2. Are the techniques of ART covered or reimbursed by (circle a, b, or c)? [a] A national health plan, [b] Private insurance, [c] No coverage. If a or b is the coverage: Complete? Partial? (Comment.)

3. The law specifies that the couple for IVF must have (circle correct answer): [a] A marriage, [b] A stable relationship, [c] No requirement, [d] ART in single women is permitted, [e] ART in lesbian couples is permitted. (Comment.)

4. The law specifies the number of preembryos which can be transferred (replaced). (Yes/No) If yes, how many and are there any exceptions? What is penalty for violation?

5. Is selective reduction allowed by the statute? (Allowed/Not allowed/Not mentioned) If not prohibited, is selective reduction practiced by programs in your country? (Yes/No/Don’t know)

6. Does the IVF law allow donor sperm to be used in IVF? (Allowed/Not allowed/Not mentioned) If allowed, are there any specific requirements?

7. Does any law (other than the IVF law) allow the use of donor sperm in non-IVF infertility? (Allowed/Not allowed/Not mentioned) If allowed, are there any requirements? If not prohibited, are donor sperm used for non-IVF infertility used by programs in your country? (Yes/No/Don’t know) (Comment.)

8. Is posthumous insemination allowed? (Allowed/Not allowed/Not mentioned) If not prohibited, is posthumous insemination used? (Used/Not used/Don’t know) (Comment.)

9. Does the law allow donor eggs to be used in IVF? (Allowed/Not allowed/Not mentioned) If yes, are there special requirements?

10. Does the statute allow the offspring to be provided on request with non-identifying information about the donor? (Allowed/Not allowed/Not mentioned) (Comment.)

11. Does the statute allow the offspring to be provided on request with identifying information about the donor? (Allowed/Not allowed/Not mentioned) (Comment.)
12. Does the statute impose on the IVF program any admonition about the welfare of any resulting offspring? (Yes/Not mentioned) (Comment.)

13. Under the statute, is cryopreservation of fertilized eggs (prezygotes to blastocysts) allowed? (Allowed/Not allowed/Not mentioned) Are there any special requirements?

14. If cryopreservation of fertilized eggs (prezygotes to blastocysts) is permitted, is there a limit to the duration of storage? (Yes/No) [If yes, how long? (Comment.)]

15. Under the statute, is cryopreservation of oocytes allowed? (Allowed/Not allowed/Not mentioned) If not mentioned, is oocyte cryopreservation practiced by programs in your country? (Yes/No/Don't know) (Comment.)

16. Is oocyte maturation allowed under the statute? (Allowed/Not allowed/Not mentioned) (Comment.)

17. Under the statute is cryopreservation of ovarian or testicular tissue (as in patients to be treated for malignancy) allowed? (Allowed/Not allowed/Not mentioned) If not mentioned, is cryopreservation of ovarian or testicular tissue practiced by programs in your country? (Yes/No/Don't know) Is ovarian or testicular tissue donation possible? (Comment.)

18. Is microinsemination (e.g., ICSI) allowed under the statute? (Allowed/Not allowed/Not mentioned) (Comment.)

19. Are other types of micromanipulation (for cloning see 20), e.g., cytoplasmic transfer, allowed under the statute? (Allowed/Not allowed/Not mentioned) (Comment.)

20. Is reproductive cloning allowed under the statute? (Allowed/Not allowed/Not mentioned) (Comment.) Is therapeutic cloning allowed under the statute? (Allowed/Not allowed/Not mentioned) (Comment.)

21. Is assisted hatching allowed under the statute? (Allowed/Not allowed/Not mentioned) If not prohibited in your country, is assisted hatching used in some programs in your country? (Yes/No/Don't know) (Comment.)

22. Is preimplantation genetic diagnosis (PGD) allowed under your statute? (Allowed/Not allowed/Not mentioned) If not prohibited in your country, is preimplantation diagnosis used by some programs in your country? (Yes/No/Don't know) (Comment.)

23. Is preimplantation genetic diagnosis (PGD) allowed for embryo screening? (Allowed/Not allowed/Not mentioned) If not prohibited, is PGD for embryo screening used in your country? (Used/Not used/Don't know) (Comment.)

24. Is IVF surrogacy, i.e., the use of gametes of both prospective parents when the female partner does not have a functioning uterus, allowed under the statute? (Allowed/Not allowed/Not mentioned) If allowed, are there special stipulations, and if so, what are they? If not prohibited, is IVF surrogacy used by some programs in your country? (Yes/No/Don't know)

25. Please point out any regulations that seem to be medically naive or even contradictory, or not in the medical best interest of the infertile couple.

26. How could the current regulations be improved?

**SECTION II—GUIDELINE IVF ONLY**

1. Are there guidelines by a medical society, religious body, or other such entity for the use of ART? (Yes/No) If yes, please supply a copy of the guidelines or indicate where one may be obtained. If yes, is any clinical surveillance carried out? (Yes/No) If yes, how is this done? (Circle correct answer.) [a] Periodic report, [b] On-site inspection, [c] Other. If other, please describe. If yes, what body carries out the clinical surveillance? If yes, is any embryological surveillance carried out? (Yes/No) If yes, how is this done? (Circle correct answer.) [a] Periodic report, [b] On-site inspection, [c] Other. If other, please describe. If yes, what body carries out the embryological surveillance? If you are reporting for a guideline country, complete the additional questions in Section II to which the guidelines apply.

2. Are the techniques of ART covered or reimbursed by (circle either a, b or c)? [a] A national health plan, [b] Private insurance, [c] No coverage.

3. The guidelines specify that the couple for IVF must have (circle correct answer): [a] A marriage, [b] A stable relationship, [c] No requirement, [d] ART in single women is permitted, [e] ART in lesbian couples is permitted. (Comment.)

4. The guidelines specify the number of preembryos that can be transferred (replaced). (Yes/No) If yes, how many and are there any exceptions?

5. Is selective reduction approved by the guidelines? (Yes/No/Not mentioned) If not prohibited (or if it is), is selective reduction practiced by programs in your country? (Yes/No/Don't know)

6. Do the IVF guidelines allow donor sperm to be used in IVF? (Yes/No/Not mentioned) If yes, are there any specific requirements?

7. Does any law or guideline (other than the IVF guidelines) speak to the use of donor sperm in non-IVF infertility? (Yes/No) If yes, are there any requirements? If no, are donor sperm used for non-IVF infertility? (Yes/No/Don't know) (Comment.)

8. Is posthumous insemination allowed? (Allowed/Not allowed/Not mentioned) If not prohibited, is posthumous insemination used? (Used/Not used/Don't know) (Comment.)

9. Do the guidelines allow donor eggs to be used in IVF? (Yes/No/Not mentioned) If yes, are there any special requirements?

10. Do the guidelines allow the offspring to be provided on request with non-identifying information about the donor? (Allowed/Not allowed/Not mentioned) (Comment.)

11. Do the guidelines allow the offspring to be provided on request with identifying information about the donor? (Allowed/Not allowed/Not mentioned) (Comment.)

12. Do the guidelines impose on the IVF program any admonition about the welfare of any resulting offspring? (Yes/Not mentioned) (Comment.)
13. Under the guidelines, is cryopreservation of fertilized eggs (prezygotes to blastocysts) permitted? (Yes/No/Not mentioned) Are there any special requirements?
14. If cryopreservation of fertilized eggs (prezygotes to blastocysts) is permitted, is there a limit to the duration of storage? (Yes/No) If yes, how long? (Comment.)
15. Under the guidelines is cryopreservation of oocytes allowed? (Yes/No/Not mentioned) If not mentioned is oocyte cryopreservation practiced by programs in your country? (Yes/No/Don’t know) (Comment.)
16. Is oocyte maturation allowed under the guidelines? (Yes/No/Not mentioned) If not mentioned, is oocyte maturation practiced by programs in your country? (Yes/No/Don’t know) (Comment.)
17. Under the guidelines is cryopreservation of ovarian or testicular tissues (as in patients to be treated for malignancy) allowed? (Allowed/Not allowed/Not mentioned) If not mentioned, is cryopreservation of ovarian or testicular tissue practiced by programs in your country? (Yes/No/Don’t know) (Comment.)
18. Is microinsemination (e.g., ICSI) allowed under the guidelines? (Allowed/Not allowed/Not mentioned) (Comment.)
19. Are other types of micromanipulation (for cloning see 20), e.g., cytoplasmic transfer, allowed under the guidelines? (Allowed/Not allowed/Not mentioned) (Comment.)
20. Is reproductive cloning allowed under the guidelines? (Allowed/Not allowed/Not mentioned) (Comment.) Is therapeutic cloning allowed under the guidelines? (Allowed/Not allowed/Not mentioned) (Comment.)
21. Is assisted hatching allowed under the guidelines? (Allowed/Not allowed/Not mentioned) If not prohibited under the guidelines, is assisted hatching used in at least some programs in your country? (Yes/No/Don’t know) (Comment.)
22. Is preimplantation genetic diagnosis allowed under your guidelines? (Allowed/Not allowed/Not mentioned) If not prohibited under the guidelines, is preimplantation diagnosis used in at least some programs? (Yes/No/Don’t know) (Comment.)
23. Is preimplantation genetic diagnosis (PGD) allowed for embryo screening? (Allowed/Not allowed/Not mentioned) If not prohibited is PGD for embryo screening used in your country? (Yes/No/Don’t know) (Comment.)
24. Is IVF surrogacy, i.e., the use of gametes of both perspective parents where the female partner does not have a functioning uterus, allowed under the guidelines? (Allowed/Not allowed/Not mentioned) If allowed, are there special stipulations, and if so, what are they?
25. Please point out any guidelines which seem to be medically naive, or even contradictory, or not in the medical best interest of the infertile couple.
26. How could the current guidelines be improved?

SECTION III—NO STATUTORY ACT OR GUIDELINES FOR IVF

1. Are there statutes, i.e., law? (national or other political subdivision) or voluntary guidelines governing the use of IVF? (Yes/No) If no, complete the additional questions in Section III.
2. Are the techniques of ART covered or reimbursed by (circle a, b, or c)? [a] A national health plan, [b] Private insurance, [c] No coverage. If a or b is the coverage: Complete? Partial? (Comment.)
3. Does prevailing custom cause the couple for IVF to have (circle correct answer): [a] A marriage, [b] A stable relationship, [c] Not an issue, [d] ART in single women is permitted, [e] ART in lesbian couples is permitted, (Comment.)
4. Does prevailing custom limit the number of preembryos which are transferred (replaced)? (Yes/No) If yes, how many and are there any exceptions? If no, please estimate the maximum number of preembryos which might be transferred.
5. Is selective reduction generally practiced? (Yes/No/Don’t know)
6. Are donor sperm used in IVF? (Yes/No) If yes, are there any specific circumstances?
7. Does any law speak to the use of donor sperm in non-IVF infertility? (Yes/No) If yes, are there any requirements? If no, are donor sperm used for non-IVF infertility? (Yes/No) (Comment.)
8. Is posthumous insemination used? (Yes/No/Don’t know)
9. Are donor eggs used in IVF? (Yes/No) If yes, are there any special circumstances?
10. If donor gametes are used is it customary for the offspring to be provided with non-identifying information about the donor? (Customary/Not customary/Varies/Don’t know) (Comment.)
11. If donor gametes are used is it customary for the offspring to be provided with identifying information about the donor? (Customary/Not customary/Varies/Don’t know) (Comment.)
12. Does custom impose on the IVF program any consideration for the welfare of any resulting offspring? (Yes/No) (Comment.)
13. Is cryopreservation of fertilized eggs (prezygotes to blastocysts) used? (Yes/No) Are there any special requirements?
14. If cryopreservation of fertilized eggs (prezygotes to blastocysts) is used, is there a consensus as to the duration of storage observed? (Yes/No) If yes, how long? (Comment.)
15. Is cryopreservation of oocytes used? (Yes/No/Don’t know) (Comment.)
16. Is oocyte maturation used? (Used/Neve used/Don’t know) (Comment.)
17. Is cryopreservation of ovarian tissue (as in patients to be treated for malignancy) used? (Yes/No/Don’t know) (Comment.)
18. Is microinsemination (e.g., ICSI) used? (Yes/No) (Comment.)
19. Are other types of micromanipulation (for cloning see 20), e.g., cytoplasmic transfer, used? (Used/Not used/Don’t know) (Comment.)
20. Is reproductive cloning used? (Used/Not used/Don’t know) (Comment.) Is therapeutic cloning used? (Used/Not used/Don’t know) (Comment.)

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21. Is assisted hatching used? (Yes/No) (Comment.)
22. Is preimplantation genetic diagnosis used? (Yes/No) (Comment.)
23. Is preimplantation genetic diagnosis used for embryo screening? (Used/Not used/Don’t know)
24. Is IVF surrogacy, i.e., the use of gametes of both prospective parents where the female partner does not have a functioning uterus, used? (Yes/No) (Comment.)
25. Which of the following best describes your opinion about statutory or voluntary guidelines for your country? Prefer as is; prefer statutory regulations; or prefer voluntary guidelines. (Comment.)

SECTION IV—GIFT

In some countries, GIFT is not included under the umbrella of regulations/guidelines covering IVF. It has been excluded on the theory that with GIFT, fertilization is not extracorporeal and, therefore, should be carried out under different regulations/guidelines. The purpose of Section IV is to document the extent of this concept.

1. For your country, do the statutes/guidelines/practice customs recognize a difference between IVF and GIFT? (Yes/No) (Comment.)
2. Where differences exist, GIFT is generally not included under the IVF umbrella of statutes/guidelines/practice customs. Is that true for your country? (True/False/Not applicable) (Comment.)
3. Is there a limit by statute/guidelines/practice customs as to the number of oocytes that are to be transferred in a GIFT procedure? (Yes/No) If yes, how many? Any exceptions?

SECTION V—THE MORAL STATUS OF THE CONCEPTUS AFTER FERTILIZATION

1. For your country, by statute/guideline/cultural practice/or recognized and prevailing religious decree, is there a recognized time during human development after which a human person is considered to exist? (Yes/No) What is this recognized time? If yes, is this time determined by: Law? Guideline? Cultural practice? Recognized and prevailing religious decree? (Comment.)
2. For your country, by statute/guideline/cultural consensus/or recognized and prevailing religious decree, is there a recognized time during human development before which a human person is considered not to exist? (Yes/No) If yes, when is it? If yes, is this time determined by: Law? Guideline? Cultural practice? Recognized and prevailing religious decree? (Comment.)

SECTION VI—EXPERIMENTATION ON THE PREEMBRYO

The preembryo can be defined as the interval of development after fertilization until the appearance of a single primitive streak, i.e., at approximately 14 days. Experimentation can be defined as any procedure that results in the destruction of the preembryo, as for example, in stem cell research.

1. For your country, by statute/guideline/cultural consensus/or recognized prevailing religious decree, is the use of human preembryos for experimental purposes an acceptable procedure? (Yes/No)
3. If yes, is special specific approval of the research proposal required, and, if so, by what body?
4. If your country defines for experiments on the developing conceptus, a developmental age other than the 14 days specified above after which experiments cannot be done, please indicate the number of days used in your country. X number of developmental days used in my country.
5. In your country is cloning possible? Reproductive cloning: Yes/No/With restrictions. Therapeutic cloning: Yes/No/With restrictions.
6. In your country is research on stem cells possible? Embryonic stem cell: Yes/No/With restrictions. Fetal stem cell: Yes/No/With restrictions. Adult stem cell: Yes/No/With restrictions.
7. In your country is gene therapy research possible? (Yes/No)