EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL AND SAVING PROVISIONS) ORDER 2009

2009 No.

1. This Explanatory Memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009 ("the Order") makes consequential amendments to both primary and secondary legislation to ensure that a woman who is a parent of a child by virtue of section 42 (civil partner at time of treatment) or 43 (agreed second female parent) of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act"), has the same rights and obligations as any other legal parent of a child. In addition, further consequential amendments (not relating to parenthood) are made to secondary legislation to implement the changes made by the 2008 Act. The Order also makes transitional and saving provisions.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 The 2008 Act makes amendments to the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") in order to reflect scientific and societal developments that have taken place since the 1990 Act was passed. For example, the 2008 Act alters the definition of embryo to ensure that it covers embryos created by new techniques not envisaged at the time of the 1990 Act. The 2008 Act also replaces existing provision under the 1990 Act to determine legal parenthood for future cases involving assisted reproduction. The 2008 Act introduces a new concept of parenthood for a mother's female partner in certain circumstances, making equivalent provision to that for opposite sex couples.

4.2 The Order makes amendments in consequence of the provisions in the 2008 Act described in paragraph 4.1 and makes transitional and saving provisions.

4.3 The substantive parenthood provisions in Part 2 of the 2008 Act were brought into force on 6th April 2009[1] along with the necessary transitional provisions. The consequential amendments relating to these provisions in the Order will be brought into force on 1st September 2009 to ensure that all the necessary changes, to, for example birth registration, are in place before a child can be born with two female parents. The other consequential amendments, not relating to parenthood, and transitional and saving provisions will come into force on 1st October 2009, along with the majority of the provisions of the 2008 Act.

4.4 The Order is subject to the affirmative procedure.

5. Territorial Extent and Application

5.1 Provisions of the Order which amend existing legislation have the same extent as the provisions being amended. All other provisions of the Order extend to the United Kingdom.

6. European Convention on Human Rights

6.1 The Minister of State for Public Health has made the following statement regarding Human Rights:

In my view the provisions of the Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009 are compatible with the Convention rights.

7. Policy background

- ***What is being done and why***

7.1 The Order follows the 2008 Act, which received Royal Assent on 13th November 2008. Some parts of the 2008 Act were brought into force on 6th April 2009 (including the parenthood provisions). It is intended that the rest of the 2008 Act, apart from the provisions relating to parental orders[2], will be commenced on 1st October 2009.

7.2 The 2008 Act made detailed changes to primary legislation and the Order follows through the policy of the 2008 Act. For example, amendments were made to the definition of "embryos" and "gametes" under the 1990 Act and the Order makes provision to ensure that these changes are carried through to other references to the definitions in secondary legislation. The Order also updates other references in secondary legislation to the provisions in the 1990 Act which have been amended by the 2008 Act including, for example, the information provisions.

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[1] The Human Fertilisation and Embryology Act 2008 (Commencement No.1 and Transitional Provisions) Order 2009 S.I.2009/479

[2] See section 54 and 55 of the 2008 Act (and associated amendments in Schedule 6)

7.3 In addition the 2008 Act sets out who is to be treated as a parent of child following assisted conception using donor sperm and makes changes to existing primary legislation to ensure that female second parents are treated in the same way as fathers. This Order carries through that policy in relation to other primary and secondary legislation.

7.4 The Annex to this Memorandum provides further detail about the provisions of the Order.

Consolidation

This Order makes amendments to primary and secondary legislation in consequence of the implementation of the 2008 Act. The legislation being amended is wide ranging and falls to various government departments. It was not, therefore, practicable to consolidate the legislation being amended to take account of the changes made by this Order

8. Consultation outcome

8.1 The Order makes transitional and consequential amendments to other legislation, and therefore the Department did not hold a full public consultation, although the policy changes were consulted on as part of the consultation on the 2008 Act. Details of this can be found on the Department of Health website. In addition, as required by section 64(5) and (7) of the 2008 Act the Department have written formally to Scotland and Northern Ireland in relation to the provisions in the Order.

9. Guidance

9.1 The Human Fertilisation and Embryology Authority ("HFEA") will communicate with licensed centres about the coming into force of the provisions of the 2008 Act including any transitional situations.

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment has not been prepared for this instrument. However an Impact Assessment was prepared on the 2008 Act itself. This is available on the Department of Health website.

11. Regulating small business

11.1 The legislation applies to small business, however it the effect on small businesses will be negligible.

12. Monitoring & review

12.1 The provisions in the Order are either consequential amendments to provisions of the 2008 Act and will therefore already be subject to a wider form of monitoring or review or are transitional provisions and will only apply for a limited period during the coming into force of the 2008 Act, it is not appropriate for ongoing monitoring or reviewing.

13. Contact

Katy Berry at the Department of Health Tel: 020 797 23055 or email: katy.berry@dh.gsi.gov.uk can answer any queries regarding the instrument.

ANNEX

1. Article 2 and Schedules 1 and 2 to the Order make consequential amendments relating to the parenthood provisions contained in Part 2 of the 2008 Act. The amendments ensure that a woman who is a parent of a child by virtue of section 42 or 43 of the 2008 Act, has the same rights and obligations as any other legal parent of a child.

2. Paragraphs 1 to 4 of Schedule 1 amend primary legislation. Amendments are made to the Marriage (Scotland) Act 1977 and the Civil Partnership Act 2004 to ensure that a second female parent under the 2008 Act is prohibited from marrying or entering into a civil partnership with her children and any connected relations in the same way that a father or mother of a child is prevented from doing. The 1990 Act is amended to ensure that if a child is subject to a Parental Order following a surrogacy arrangement, and has a second female parent under the 2008 Act, that parent's consent will be needed before the order can be made. A reference in the Children Act 1989 is also amended to reflect changes made to that Act by the 2008 Act, which enable second female parents to acquire parental responsibility.

3. Paragraphs 5 to 19 of Schedule 1 make amendments to secondary legislation. Paragraphs 5, 6 and 8 update regulations relating to births on planes, hovercrafts and at sea, to make provision for registration of second female parents in the same way as for all other births. Paragraph 7 makes amendments to the Registration (Births, Still-births and Deaths) Regulations (Northern Ireland) 1973 to enable a second female parent under the 2008 Act to be registered as the parent of their child on the birth register[3]. Paragraph 9 extends the information that must be recorded about the birth of a British citizen outside the UK to include information about a child's second female parent, where applicable. Paragraph 10 extends British protected person status to children of second female parents, in certain circumstances.

4. Paragraph 11 updates court rules relating to children and young people to ensure that a second female parent is notified of certain court proceedings involving her child, in the same way that a father must be notified.

5. Paragraph 12 and Schedule 2 to the Order amend the Children (Parental Responsibility Agreement) Regulations (Northern Ireland) 1996 to enable a second female parent to acquire parental responsibility for a child. Paragraphs 13, 14, 16, 17 and 19 update regulations for England and Wales relating to adoption to make provision for children with a second female parent. Paragraph 15 amends the Gender Recognition Regulations 2005 to reflect the changes made to other registers to include second female parents. Paragraph 18 amends regulations relating to immigration to enable a person to claim a certificate of entitlement through their second female parent in the same way that they are able to claim through their father.

6. Schedule 3 to the Order contains other consequential amendments, not relating to parenthood. Amendments are made by paragraphs 2, 5 and 6 to update references to the terms "embryos" and "gametes" in legislation regulating genetically modified organisms and the disclosure of information in relation to assisted conception. These changes reflect amendments made to these definitions in the 1990 Act by the 2008

[3] Equivalent amendments will be made for England and Wales by separate instruments.

Act. Amendments are also made to regulations relating to data protection and health records to reflect amendments made by the 2008 Act to the information provisions in the 1990 Act (paragraphs 1, 3 and 4 of Schedule 3). Paragraphs 7 and 8 amend regulations relating to human tissue and the quality and safety of embryos and gametes to ensure that the terms used reflect the 1990 Act as amended by the 2008 Act.

7. Schedule 4 makes transitional and saving provisions. Paragraph 1 ensures that any treatment licence granted on or before 30th September will be governed by the provisions of the 1990 Act, as amended by the 2008 Act, including the new definitions of "embryos" and "gametes". However provision is made to ensure existing consents in relation to treatment remain valid, as do licences authorising embryo testing, notwithstanding the additional requirements introduced by the 2008 Act. Provision is also made so that if a woman has presented for treatment services on or before 30th September 2009, the treating clinic will have to consider the need for a father of any child that might be born, rather than the new test of the need of any child for supportive parenting.

8. Paragraph 2 ensures that any research licence granted on or before 30th September will be governed by the provisions of the 1990 Act, as amended by the 2008 Act. However the new definitions of embryos and gametes will not apply, nor will the obligations relating to human admixed embryos (as these entities will continue to be regulated as human embryos). If a research project commenced on or before 30th September 2009 under an existing research licence complies with the consent requirements under the 1990 Act, it will not be necessary to meet the new consent requirements introduced by the 2008 Act. However researchers who are using human cells to create embryos will have to ensure that the embryos cannot be traced back to the cell donors. If a licence holder intends to derive stem cells for human application under an existing research licence they will need to re-apply for a licence to ensure they are complying with the requirements of the EU Directive – Setting Quality and Safety Standards for Human Tissue and Cells for use in Human Application[4].

9. Paragraphs 3 and 4 ensure that any storage or non medical fertility licence granted on or before 30th September will be governed by the provisions of the 1990 Act, as amended by the 2008 Act, including the new definitions of embryos and gametes. However provision is made to ensure any existing consents do not need to comply with the new requirements introduced by the 2008 Act.

10. Paragraph 5 makes transitional provision to ensure that any outstanding applications to the HFEA by a person to find out if they are related to someone they intend to marry will be treated as a request under the new provisions on information introduced by the 2008 Act. This ensures that the request for information is still valid and will be responded to by the HFEA.

11. Paragraph 6 ensures that the HFEA can continue to exercise their powers to retain things taken under powers in the 1990 Act and to exercise any warrants granted under those powers. Any warrants exercised on or after 1st October 2009 will have to comply with the new safeguards introduced by the 2008 Act.

[4] 2004/23/EC

12. Paragraphs 7, 8 and 12 make provision so that any outstanding inspections by the HFEA, applications relating to the revocation or variation of a licence, and suspensions are dealt with under the new provisions introduced by the 2008 Act. In cases where a licence committee have already reached a proposal in relation to the refusal, variation or revocation of a licence the provisions of the 1990 Act will apply, with some modifications to ensure that the decision of the licence committee can be reconsidered in accordance with the new provisions on reconsideration (paragraph 9).

13. Paragraph 10 makes provision to ensure that any outstanding appeals that have a hearing date, or are being heard, are dealt with under the 1990 Act provisions and the Human Fertilisation and Embryology Authority (Licence Committee and Appeals) Regulations 1991[5], unless the parties agree to be governed by the new provisions. All other appeals will be dealt with under the new provisions inserted by the 2008 Act and the Human Fertilisation and Embryology (Appeals) Regulations 2009[6] with some modifications to avoid duplication of obligations. Any outstanding notices of the outcome of an appeal shall be given in accordance with the 1990 Act prior to amendment.

14. Paragraph 11 ensures that any decisions of the Authority can be appealed to the High Court or Court of Session in accordance with the new provisions introduced by the 2008 Act.

15. Paragraph 13 makes provision to save the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 ("the 2004 Regulations")[7] and section 31 of the 1990 Act for the purpose of amending or revoking the 2004 Regulations. This means that the disclosure of donor information from 1st October 2009 will continue to be regulated by the 2004 Regulations.

[5] S.I. 1991/1889
[6] These regulations will be debated along side this Order.
[7] S.I. 2004/1511