EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (SUPPLEMENTARY PROVISION) ORDER 2009

2009 No. 2478

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 (Supplementary Provision) Order 2009 ("the Order") makes supplementary provision to section 15(3) of the Human Fertilisation and Embryology Act ("2008 Act"), under section 64(1) of the 2008 Act, for specific cases of embryos remaining in storage from 1 October 2009 in relation to which the statutory storage period of five years has expired.

2.2 Section 15(3) amends the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") to enable embryos to be stored for ten years from the date they were placed into storage. Prior to this amendment embryos could only be stored for five years. The extension will apply to all embryos lawfully stored on 1 October 2009. It will not extend to the group of embryos covered by this Order because their 5 year storage period will have expired before 1 October 2009. This Order will make supplementary provision to enable these "out-of-time" embryos to be held in storage up to a maximum of 10 years from the date on which they were put into storage. The new 10 year statutory storage period will only apply from 1 October 2009.

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

3.1 It is not possible to observe the 21 day rule because following the making of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ("the 2009 Regulations") on 25 June 2009 there have been significant representations made to the Department. These related to embryos intended for use by couples who need to enter into surrogacy arrangements, where those embryos will have run out of storage time before the regulations are brought into force on 1 October 2009.

3.2 Such embryos are subject to a maximum five year statutory storage period under the 1990 Act and cannot benefit from the extended storage periods available to those with infertility under the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 ("1996 Regulations"). The 2009 Regulations replace the 1996 Regulations and enable embryos stored for surrogacy to be stored for up to 55 years.

3.3 The concerns raised relate to a small group of "out-of-time" embryos which have been stored for longer than the 5 year statutory storage period. The provisions of the 2009 Regulations could not be extended to them and they would have to be destroyed. These cases involve the use of a surrogate, which may take longer that the 5 years storage allowed under the 1990 Act to arrange.

3.4 The Department has given urgent consideration as to whether any provision could be made for this group of out-of-time embryos. This Order reflects the outcome of detailed legal and policy considerations. Because of the time needed to consider whether it would be possible to address concerns raised within the powers available, it has not been possible to prepare the Order in time to observe the 21 day rule.

4. Legislative Context

4.1 From 1 October 2009, section 15(3) of the 2008 Act extends the maximum storage period for embryos from 5 years to 10 years. This Order is being made as supplemental to this provision of the 2008 Act. It will enable embryos that are in storage on 1 October 2009, but which on that date have been stored past the expiry of the five year statutory storage period, to benefit from a ten year maximum statutory storage period. This will only take effect in relation to these embryos from 1 October 2009, and so will not affect the status of any past storage. The ten year period will be calculated, as for all other embryos, as starting on the date the embryo was first placed into storage.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

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

7.1 The Human Fertilisation and Embryology Act 1990 sets out a 5 year maximum storage period for embryos. This may be extended under specific circumstances. The circumstances are set out in the 1996 Regulations, which allow extension for reasons related to medical infertility. The 1996 Regulations do not permit extension in cases where the embryo is to be used in treatment with a surrogate. This reflected concerns about surrogacy at the time the legislation was introduced.

7.2 The 2008 Act amended the maximum storage period for embryos to 10 years, to bring it in line with that of gametes (sperm and eggs). From the 1 October 2009, all embryos being put into storage will benefit from an initial 10 year

storage period. Embryos currently within the present storage limit of five years will also benefit from the 10 years.

7.3 The 1996 Regulations have also been reviewed and will be replaced by the 2009 Regulations. The 2009 Regulations, which come into force on the 1 October 2009, will enable storage to be extended in cases where the embryo is to be used in treatment with a surrogate, provided that specific criteria relating to infertility are fulfilled.

7.4 However, there are currently a number of cases where embryos remain in storage even though their statutory storage period has expired. The embryos are intended for use in treatment with a surrogate, and the woman of the commissioning couple suffers from premature infertility. These cases cannot currently benefit from the extended maximum storage period under the 1996 Regulations. As the embryos are being stored outside the current maximum storage period it is also not possible for them to benefit from the provisions in the 2009 Regulations. Nor, legally, do they benefit automatically from the provision in the 2008 Act which replaces the 5 year maximum period with a 10 year period.

7.5 To prevent this group of "out-of-time" embryos from being destroyed this Order makes supplemental provision to the 2008 Act. The Order will enable embryos in specific cases to be stored from 1 October 2009 for 10 years, beginning with the date they were placed into storage.

7.6 The Order will affect a very small group of people. However, it may provide an opportunity for those people to have their own genetic child.

8. Consultation outcome

8.1 Although this Order was not subject to consultation due to time constraints, both the 2008 Act and the 2009 Regulations were subject to extensive consultation. The Order represents the wishes expressed in a range of representation for these out-of-time embryos not to be destroyed. These representations include Parliamentarians, people affected and their representatives

9. Guidance

9.1 The Human Fertilisation and Embryology Authority ("HFEA") will update guidance on storage for clinics and patients to ensure that they are aware of the Order.

10. Impact

10.1 The impact on business, charities or voluntary bodies and the public sector is minimal as the Order will only affect a small number of people and a small number of the centres which are storing the embryos already. The patients involved store embryos voluntarily.

10.2 A full impact assessment was undertaken on the 2009 Regulations. It can be found here: http://www.opsi.gov.uk/si/si2009/uksi_20091582_en_1

11. Regulating small business

11.1 The legislation will apply to a minimal number of small businesses. The majority of IVF clinics are private businesses. The changes made by the Order will affect a very small group of patients and an equally small number of IVF clinics which are storing the embryos already. Storage is voluntary, and any increased costs associated with storage will be met by the people who choose to store and in some cases by the NHS.

12. Monitoring & review

12.1 The HFEA inspects each centres licensed to store gametes and embryos to ensure that the relevant legislation is being complied with. They will continue to do this when the 2009 Regulations, the Order and the 2008 Act come into force and part of their inspections may include checking the conditions for which extension to storage is being granted.

12.2 The HFEA's discharge of its statutory functions will be monitored by the Department of Health by means of a quarterly accountability review at official level and also an annual accountability review conducted by the Minister of State for Public Health.

13. Contact

13.1 Stephanie Croker at the Department of Health Tel: 0207 9723054 or email: Stephanie.croker@dh.gsi.gov.uk can answer any queries regarding the instrument.