

EXPLANATORY MEMORANDUM TO
THE HUMAN FERTILISATION AND EMBRYOLOGY (STATUTORY
STORAGE PERIOD FOR EMBRYOS AND GAMETES) (AMENDMENT)
REGULATIONS 2009

2009 No. 2581

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 (Statutory Storage Period for Embryos and Gametes) (Amendment) Regulations 2009 (“the Regulations”) fulfil two purposes. Firstly, the Regulations enable embryos that will remain in storage from 1st October 2009, by virtue of the Human Fertilisation and Embryology (Supplemental Provision) Order 2009 (“the Order”), to benefit from the extended storage periods set out in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (“the 2009 Regulations”) provided they fulfil the conditions set out in those Regulations.
- 2.2 Secondly, the Regulations amend the 2009 Regulations to clarify that the reference to a “statutory storage period” is to the maximum period that a licence may specify that the embryo or gamete in question may be stored. This amendment ensures that the wording of the 2009 Regulations is in line with the wording of the storage provisions in the Human Fertilisation and Embryology Act 1990 (“the 1990 Act”).

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

- 3.1 It has not been possible to observe the 21 day rule because following the making of the 2009 Regulations on 25 June 2009 there have been significant representations made to the Department. These representations related to embryos in storage that are intended for use by couples who need to enter into surrogacy arrangements, where those embryos will have run out of storage time before the 2009 Regulations are brought into force on 1st October 2009.
- 3.2 The Department brought forward the Order to ensure these “out-of-time” embryos could remain in storage for up to 10 years. Following the making of the Order it was necessary to make provision to fulfil the Government policy that these embryos should be able to benefit from extended storage periods under the 2009 Regulations, provided that the criteria set out in the 2009 Regulations are met.
- 3.3 Because of the time needed to consider whether it would be legally possible to address the concerns raised, there has not been sufficient time to prepare the Regulations in time to observe the 21 day rule.

4. Legislative Context

- 4.1 From 1st October 2009, section 15(3) of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) will amend section 14 of the 1990 Act to extend the maximum storage period for embryos from 5 years to 10 years.
- 4.2 The Order was made to ensure that embryos subject to the 5 year storage period, where that period expired before 1st October 2009, would be able to benefit from a 10 year storage period from 1st October 2009, calculated from the date they were placed in storage.
- 4.3 The 2009 Regulations are made under section 14(5) of the 1990 Act and extend the maximum 10 year storage period in specified circumstances.
- 4.4 These Regulations amend the 2009 Regulations to enable embryos that remain in storage by virtue of the Order to benefit from the extended storage periods set out in the 2009 Regulations, provided that the criteria for extension are fulfilled. These Regulations also ensure the wording of the 2009 Regulations is consistent with the storage provisions in section 14 of the 1990 Act.

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 Human Fertilisation and Embryology (Statutory Storage Periods for Embryos) Regulations 1996 (“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 amends the maximum storage period for embryos to 10 years, to bring it in line with that of gametes (sperm and eggs). From the 1st 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 1st 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 an Order was made to make supplemental provision to the 2008 Act. This Order enables 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 However, the Order does not automatically mean that this group of embryos will benefit from the extended storage periods set out by the 2009 Regulations. These Regulations clarify that for this small group of people whose embryos remain in storage under the Order, if they fulfil the criteria set out by the 2009 Regulations, they may extend the storage period of their embryos to a maximum of 55 years.

8. Consultation outcome

- 8.1 Although these Regulations were not subject to consultation due to time constraints, both the 2008 Act and the 2009 Regulations were subject to extensive consultation. The Regulations represent the wishes expressed in a range of representations for these out-of-time embryos to benefit from the same extended storage periods as those embryos that are not “out-of-time” embryos. 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 Regulations.

10. Impact

- 10.1 The impact on business, charities or voluntary bodies and the public sector is minimal as the Regulations 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 Regulations 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 Regulations, 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.