Department of Health

Memorandum to the Health Committee

Post-Legislative Assessment of the Human Fertilisation and Embryology Act 2008

Cm 8823

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POST-LEGISLATIVE ASSESSMENT OF THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 2008

Introduction

1. This memorandum provides a preliminary assessment of the Human Fertilisation and Embryology Act 2008 (2008 Ch. 22) and has been prepared by the Department of Health for submission to the Health Committee. It is published as part of the process set out in the document *Post Legislative Scrutiny – The Government's Approach* (Cm 7320).

Objectives of the Human Fertilisation and Embryology Act 2008

2. The primary purpose of the Human Fertilisation and Embryology Act 2008 (2008 Act) was to update the provisions of the Human Fertilisation and Embryology Act 1990 (1990 Act), which regulates the provision of assisted reproduction treatments and services and human embryo research, while retaining the basic principles enshrined in that legislation: that regulated activities are carried out in a safe and ethical manner.

3. The 1990 Act, which came into force across the United Kingdom in August 1991, was ground breaking legislation. For the first time anywhere in the world, a regulatory framework was applied to the delivery of scientifically novel, e.g. *in vitro* fertilisation (IVF) or ethically sensitive, e.g. donor insemination, assisted reproduction treatments and services and human embryo research. The 1990 Act also created the UK-wide national regulatory body for these activities, the Human Fertilisation and Embryology Authority (HFEA), which was established as a non-departmental public body.

4. In July 2007, the 1990 Act was amended to implement the provisions of three European Union Directives setting quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application[1], as they apply to sperm, eggs and embryos, making

1 Directive 2004/23/EC sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application. Commission Directive 2006/17/EC (implementing Directive 2004/23/EC) sets certain technical requirements for the donation, procurement and testing of human tissue and cells. Commission Directive 2006/86/EC (also implementing Directive 2004/23/EC) sets requirements for traceability, notification of serious adverse reactions and events and certain technical requirements for coding, processing, preservation, storage and distribution of human tissue and cells. The provisions of the Directives were implemented in the UK by amendments to the Human Fertilisation and Embryology Act 1990 by means of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007, S.I. 2007/1522, made under subsection 2(2) of the European Communities Act 1972. The amendments came into force for enabling purposes on 25 May 2007 and for all other purposes on 5 July 2007.

the HFEA the UK Competent Authority for the Directives.

5. The 1990 Act had stood the test of time well, in view of the fast moving area of science it regulated, and was still considered to be fit for purpose. However, scientific developments in the fields of treatment and research since the 1990 Act came into force, together with legislative changes in other, related areas, such as the establishment of civil partnerships that impact upon legal parenthood, meant that it was the appropriate time to review the 1990 Act to consider where the provisions would benefit from being updated. In developing its proposals, the Government took account of the recommendations of the House of Commons Science and Technology Committee's inquiry into human reproductive technologies and the law.

6. The review commenced in 2004. A public consultation on the Government's proposals for revisions to the legislation took place in the latter half of 2005. A White Paper was published in December 2006 containing the Government's policy proposals[2]. A draft Bill was published for scrutiny by a Joint Committee of both Houses in May 2007 before its introduction into the House of Lords. The Bill began its passage though both Houses of Parliament on 8 November 2007[3], completing its passage in October 2008. The 2008 Act received Royal Assent on 13 November 2008. The exercise to update the legislation in this area was concluded in 2010, when the final pieces of secondary legislation were brought in to force.

Implementation

7. The 2008 Act is in three parts:

i. Part 1 amends and updates the provisions of the 1990 Act.

ii. Part 2 replaces provisions in the 1990 Act to determine legal parenthood for future children born as a result of assisted reproduction techniques, including those born as a result of a surrogacy arrangement.

iii. Part 3 amends the Surrogacy Arrangements Act 1985, together with other miscellaneous provisions.

8. The provisions of the 2008 Act were mainly commenced in two groups. The primary commencement date was 1 October 2009 but some key provisions, including those relating to parenthood, disclosure of information, licensing procedures and appeals, new licence conditions and powers for 3rd parties to discharge statutory functions on behalf of the HFEA were commenced on 6 April 2009. A small number of provisions were commenced in September 2009 and April 2010. A full list of commencement dates is at Annex A. Otherwise, there remain regulation making powers that have not been exercised and these are discussed below in paragraph 10.

9. The 2008 Act introduced regulation and order making powers. The following pieces of secondary legislation have been made under the 2008 Act (to date):

2 *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos* published December 2006 (Cm 6989).

3 First Reading in the House of Lords.

Policy Area	Statutory Instrument	Description
Disclosure of identifying information	The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (SI 2010/995) *Came into force: 6 April 2010*	Establishes an application process (mirroring that created by s.251 of the National Health Service Act 2006) to enable researchers to apply for access to identifying information held on the HFEA's register of patients, donors, treatments and resulting offspring, for use in research, where it is not practicable to obtain consent to the disclosure from the persons to whom the information relates. The HFEA is the approving body.
Legal parentage	The Human Fertilisation and Embryology (Parental Orders) Regulations 2010 (SI 2010/985) *Came into force: 6 April 2010*	Applies adoption legislation to parental orders, in surrogacy cases, to determine the legal status of a child who is the subject of a parental order, establishes the Parental Order Register and ensures that the welfare of the child is paramount in any decision made to grant a parental order.
	The Human Fertilisation and Embryology (Parental Orders) (Consequential, Transitional and Saving Provisions) Order 2010 (SI 2010/986) *Came into force: 6 April 2010*	Makes amendments in consequence of the repeal of the provision relating to parental orders under the 1990 Act and the commencement of the new parental order provision under the 2008 Act. Makes transitional provision for any applications outstanding at the time the new provisions came into force. Saves various provisions of adoption legislation to apply to parental orders.

Policy Area	Statutory Instrument	Description
Warrants	The Human Fertilisation and Embryology (Procedures on Applications and Execution of Warrants) Regulations 2010 (SI 2010/726) *Came into force: 6 April 2010*	Enables a licence committee of the HFEA to require the production of evidence or attendance by a witness at a hearing. Also sets out the information that must be included in a statement that is given to the occupier of the premises ("the appropriate statement"), when a warrant is executed.
Storage of gametes and embryos	The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009[4] (SI 2009/1582) *Came into force: 1 October 2009*	Sets out the criteria that must be fulfilled for gametes and embryos to remain in storage for longer than the statutory storage period of 10 years contained in the 1990 Act.
	The Human Fertilisation and Embryology (Supplementary Provision) Order 2009 (SI 2009/2478) *Came into force: 1 October 2009*	Extends the statutory storage limit for certain embryos in storage on 1 October 2009.
Licensing	The Human Fertilisation and Embryology (Special Exemption) Regulations 2009 (SI 2009/1918) *Came into force: 1 October 2009*	Provides exemptions to the requirement that keeping or storing human embryos can only be done under a licence from the HFEA – for (i) the investigation of and proceedings relating to an offence, and (ii) storage in specified circumstances, such as for research purposes (regulations do not apply to human admixed embryos).

4 Amended by The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Amendment) Regulations 2009, S.I. 2009/2581.

Policy Area	Statutory Instrument	Description
	The Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009 (SI 2009/1892) *Came into force: article 2 and Schedules 1 and 2, 1 September 2009, for all other purposes, 1 October 2009*	Includes transitional and saving provisions related to HFEA licences in force on 30 September 2009. Also saves The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 to ensure they remained in force. Makes consequential amendments to other legislation in relation to the introduction of provisions in the 2008 Act, e.g. to ensure that legislation refers to a second female parent.
	The Human Fertilisation and Embryology (Appeals) Regulations 2009 (SI 2009/1891) *Came into force: Regulation 4-6 and 2 in so far as it relates to them, 16 July 2009, remainder, 1 October 2009*	Establishes the procedure for hearing appeals against HFEA Licence Committee/Executive Licencing Panel decisions, including the establishment of an independent Appeals Committee.
	The Human Fertilisation and Embryology (Procedures for Revocation, Variation or Refusal of Licences) Regulations 2009[5,6] (SI 2009/1397) *Came into force: 1 October 2009*	Establishes the procedures to be followed by HFEA in refusing a licence application and varying or revoking an existing licence.

5 The S.I. was made by the Human Fertilisation and Embryology Authority itself under the regulation making powers conferred on it by subsection 19(6) of the Human Fertilisation and Embryology Act 1990.

6 Amended by The Human Fertilisation and Embryology (Procedures for Revocation, Variation or Refusal of Licences) (Amendment) Regulations 2009, S.I. 2009/2088.

10. The 2008 Act introduced into the 1990 Act a number of regulation making powers that have not, to date, been used. These primarily relate to the ability to make regulations in the future to amend the 1990 Act to reflect scientific developments, such as the power in section 1(6) to extend the meaning of "gametes" and "embryos". In this case the regulations are affirmative, requiring the approval of both Houses of Parliament[7].

Mitochondrial donation

11. Regulations are currently under development relying on the powers under sections 3ZA[8](*Permitted eggs, permitted sperm and permitted embryos*) and 35A (*Mitochondrial donation*) of the 1990 Act (as inserted by the 2008 Act). The regulations would enable the use in treatment of techniques that would prevent the transmission of a serious mitochondrial disease from mother to child by the use of enucleated eggs or embryos from unaffected donors. During the passage of the Human Fertilisation and Embryology Bill the Government of the day gave an assurance that such regulations would not be made until any proposed technique was considered effective and safe for use in treatment.

12. In 2010 the Government was approached by researchers working in this field and asked to consider making such regulations. An examination of the newly developed treatment techniques was undertaken by an Expert Panel, convened by the HFEA. It considered that two techniques showed promise but that further work needed to be undertaken to demonstrate that they were safe for use in treatment. Whilst further experiments were carried out, the HFEA, in association with the Sciencewise Expert Resource Centre[9], undertook a public dialogue/consultation exercise to ascertain the view of stakeholders and the wider public on the suitability of allowing such treatments to take place. The consultation was undertaken because some people consider that the procedure is controversial.

7 Regulation making powers under the 1990 Act, as inserted by the Human Fertilisation and Embryology Act 2008, that are yet to be exercised are:
- Subsection 1(6): to revise definitions of "embryo", "eggs", "sperm" or "gametes".
- Subsection 3ZA(5): to revise definition of "permitted egg" and "permitted embryo" to allow mitochondrial donation procedures to take place (also see section 35A).
- Subsection 4A(5): further prohibitions on keeping or using human admixed embryos.
- Subsection 4A(11): power to amend definition of human admixed embryos
- Subsection 24(4B): directions in relation to activities involving genetic material of animal origin.
- Section 33C: exceptions to the prohibition on disclosure of identifying patient information.
- Section 35A: power to make regulations to give effect to various provisions relating to donor information and consent in the event that the power contained in section 3ZA is exercised.
- Paragraph 1ZC of Schedule 2 to the 1990 Act: amendments to provisions on embryo testing.
- Paragraph 3A(1)(c) of Schedule 2 to the 1990 Act: extending purposes for which a research licence may be granted.

8 Power is in subsection 3ZA(5) of the Human Fertilisation and Embryology Act 1990, as amended.

9 The Sciencewise Expert Resource Centre for Public Dialogue in Science and Innovation (Sciencewise-ERC) is funded by the Department for Business, Innovation & Skills. It aims to help policy makers commission and use public dialogue to inform policy decisions involving science and technology issues.

13. The HFEA reported the findings of this exercise in March 2013, together with an updated review of the science[10]. The dialogue/consultation exercise had a number of strands, including workshops, focus groups and an open, web-based questionnaire. Following this exercise the HFEA reported that, overall, the balance of views from stakeholders and the members of the public who took part was that the treatment techniques should be allowed but their use should be carefully controlled, while recognising that there was a body of opposition to allowing these procedures in the UK. The updated review of the research indicated that there was still no evidence to suggest that either of the proposed treatment techniques was unsafe but the Expert Panel recommended that additional experiments be carried out.

14. Based on this advice, Ministers decided to take the next step in this process and prepare draft regulations for public consultation. The consultation was published on 27 February 2014. The consultation period closes on 21 May 2014. If made, the regulations would be subject to the affirmative resolution procedure.

Legal issues

15. The policy behind the 1990 Act has withstood legal challenges, which often amounted to a test of the scope of the definitions in the Act as against scientific developments, such as whether the term "embryo" covered embryos created by means other than fertilisation[11], or whether the Act permitted certain activities, such as carrying out pre-implantation genetic diagnosis with human leukocyte antigen testing, a process that enables embryos to be selected that are a tissue match for a sick older child (known as "saviour siblings") so that stem cells in the cord blood of the new child can be used to treat their older sibling[12]. The 2008 Act provided an opportunity to address any areas which had the potential for uncertainty with regard to meaning or scope. Since implementation there have been no significant legal issues or actions with regard to the amended 1990 Act or the parenthood provisions contained in the 2008 Act, as far as the Government is aware[13].

Post legislative reviews

16. The Government is not aware of any external review of the 2008 Act or the amended 1990 Act since Royal Assent.

17. In July 2010 the Department of Health published the report of its review of its arm's-length bodies. The report recommended that the HFEA be retained in the short-term but that its functions should be transferred to other regulatory bodies, and the Authority abolished, by the end of the current Parliament (2015). Among the

10 *Mitochondria replacement consultation: Advice to Government*, published by the HFEA on 20 March 2013.

11 *R. (on application of Quintavalle) v Human Fertilisation and Embryology Authority [2003] 2 A.C. 687*

12 *R. (on application of Quintavalle) v Human Fertilisation and Embryology Authority [2005] 2 A.C. 561*

13 In January 2014 the Family Division of the High Court heard a claim from Mrs Elizabeth Warren who is seeking a ruling from the Court relating to the period of time that her late husband's sperm can remain in storage. The statutory maximum storage period for gametes has remained the same since the 1990 Act came into force in 1991. The limited exceptions to this storage period are set out in The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 made under that Act. The requirements for the storage period for gametes are not related to 2008 Act amendments. On 6 March the Court found in favour of Mrs Warren's claim. The Government is considering the detail of the judgment and its implications to determine the most appropriate course of action.

candidate bodies to receive HFEA functions were the Care Quality Commission and the new Health Research Authority. A public consultation took place from 28 June to 28 September 2012, seeking views on where the HFEA functions might lie in the future. The respondents to the consultation were overwhelmingly of the view that the HFEA should be retained and continue to discharge the functions given to it by the 1990 Act. However, respondents were also strongly of the view that there should be a review of the way in which the HFEA conducted its business.

18. In its response to the consultation[14] the Government announced in January 2013 that the HFEA would be retained with its existing statutory functions. It was also announced that an independent review of the Authority (and also the Human Tissue Authority) would be carried out by Mr Justin McCracken, then Chief Executive of the Health Protection Agency. Mr McCracken reported to Government in April 2013 making a number of recommendations regarding the future delivery of HFEA's business[15]. However, none of his recommendations concerned the legislation in the area of human fertilisation and embryology, having found that there was almost universal praise for the legislation and that it was considered fit for purpose[16].

19. In its response[17] the Government accepted Mr McCracken's recommendations, which have also been welcomed by the HFEA[18].

Preliminary assessment of the effect of the Human Fertilisation and Embryology Act 2008

Effectiveness of provisions

20. The Government believes that the 2008 Act has been successful in meeting its aim to update the provisions of the 1990 Act and make provision for legal parenthood, including same sex couples, in cases of assisted reproduction. It believes that the care taken to consult stakeholders, throughout the development of the 2008 Act, has been key to this.

21. Mindful of the sensitivity of the issues the 1990 Act regulated, the Government, in deciding to review the legislation, was committed to ensuring that its proposals should be subject to comprehensive consultation with stakeholders, the wider public and Parliament so that, as far as possible, there would be a consensus on the suitability of any revisions.

22. Full account was taken of the comments received. Notably, an initial proposal intended to reflect the requirements of the EU Tissue and Cells Directives[19], by bringing all activities involving the use of human tissue, including gametes and embryos for human application, within the remit of a new regulatory body (the Regulatory Authority for Tissue and Embryos, "RATE"), was set aside when the respondents

14 *Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority*, published 25 January 2013.

15 *Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority: An Independent Report to the Parliamentary Under Secretary of State and the Minister for the Cabinet Office by Justin McCracken*, published 22 April 2013.

16 Paragraph 4.5.

17 *Response to the review of the HFEA and HTA: Government response to the report of the independent review of the Human Fertilisation and Embryology Authority and the Human Tissue Authority by Justin McCracken*, published 17 July 2013.

18 HFEA press release 17 July 2013.

19 See note 1.

to the public consultation and the members of the Joint Committee on the Human Tissue and Embryos (Draft) Bill[20], at pre-legislative scrutiny, did not support the change.

23. Consultation was also a key feature of the development of secondary legislation made under the 2008 Act. A sensitive Statutory Instrument, The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010, which created a scheme for the release of identifying information held by the HFEA where it was not practicable to obtain consent to the disclosure from the persons to whom the information related, was subject to two rounds of consultation, the second round to seek comments on changes to the draft regulations made as a result of the first round, to ensure the Regulations created a robust mechanism for disclosure while still protecting the interests of the data subjects.

24. The Government believes that the care taken in the development of the legislation has meant that provisions contained in the 2008 Act legislation enjoy a wide level of support within the assisted reproduction sector, an assessment borne out by the evidence given to Mr McCracken during his review of the HFEA. This view is further supported by the fact that there has been no representation made to the Department of Health on the need to amend or repeal any of the new provisions.

25. Certain aspects of the 2008 Act were particularly contentious during the consultation exercises and also during the passage of the Bill through Parliament. These are discussed below.

20 At the time of pre-legislative scrutiny, the draft Bill was known as the Human Tissue and Embryos Bill. When the Government decided to set aside the proposal to create a new regulatory body, which was a key function of the Bill, the name of the draft Bill was changed to the Human Fertilisation and Embryology Bill.

Status of human gametes and embryos

26. It became clear very early in the review that the general public's views on the status of the human embryo had not changed since the 1980s when the 1990 Act was under development. The public was still strongly of the view that gametes and embryos needed to be handled far more sensitively than other human tissue and that their use in treatment or research should still be subject to strict controls. The amendments to the 1990 Act, made by the 2008 Act, carry forward these fundamental principles.

27. As indicated earlier, the revised legislation aimed to remove any possibility of ambiguity about what types of gametes or embryos might be used in treatment, to take account of the possibility of the development of artificial gametes at some future point and to confirm that only embryos created by fertilisation may be used in fertility treatment. The gametes and embryos that can be used for treatment purposes are now defined in the 1990 Act as "permitted" eggs, sperm or embryos. As indicated in paragraph 10 of this Memorandum, a regulation making power has been inserted into the 1990 Act to allow the definitions of permitted eggs, sperm or embryos to be amended, if necessary, in the future.

28. The provisions appear to have had the desired effect. In the early 2000s there were legal test cases related to the ability to use certain types of embryos in treatment, including whether the 1990 Act actually prohibited the use of cloned embryos in treatment. There have not been any further legal actions of this type since the 2008 Act was implemented.

Welfare of the child and parenthood

29. The requirement for clinics to consider the welfare of any child that might be born as a result of treatment, or any existing child that might be affected by the birth, before making the offer of treatment[21] has been a cornerstone of the 1990 Act and is retained by the 2008 Act amendments. This requirement was never intended to be a test of the patients' potential to be "good parents", as many have assumed. Rather, as treatment may result in a child that would otherwise not be brought into that environment, it was to examine whether there were any factors that might indicate that treatment would not be appropriate in that particular case. This is why the assessment has been retained.

30. The significant change here was the replacement of the requirement to consider the child's "need for a father", as part of considering their welfare, with the "need for supportive parenting" to reflect the introduction of the legal status of second female parents. During the passage of the 2008 Act concerns were raised that removing the reference to fathers would diminish the role of the father in a child's life. However, Parliamentarians ultimately agreed that this was not the case. The original requirement was never about a single woman or female same sex couple being able to produce a man to enable the clinic to tick a box. Rather, it was about ensuring a child would have access to the support it would need in its development. That is why the legislation was changed, to make that principle more prominent and to reflect the fact that studies have indicated that a child generally benefits from supportive parenting, irrespective of the sex of the parents. The Department of Health has not been made aware of any on-going difficulties with the revised requirements.

31. Part 2 of the 2008 Act concerns the legal parenthood of children born as a result of assisted reproduction after the Act came into force. It largely retains the provisions previously contained in the 1990 Act but, importantly, also enables female same sex couples to be recognised as the legal parents of a child. It also introduces parenthood agreements that clarify who the legal father or second female parent of a child will be where a couple who are not married or in a civil partnership access assisted reproduction services at a regulated clinic. The parenthood provisions have recently been modified to take account of the Marriage (Same Sex Couples) Act 2013, which received Royal Assent on 17 July 2013[22]. This will confer the same rights on people who enter into a same sex marriage as those in a heterosexual marriage. Again, the Department of Health is not aware of any on-going difficulties with the new parenthood provisions in the 2008 Act.

21 Section 13 (*Conditions of licences for treatment*): "(5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.".

22 Paragraphs 37-41 of Schedule 7 to the Marriage (Same Sex Couples) Act 2013 (2013 Ch30) modify sections 35, 40, 42 and 46 of the 2008 Act, on parenthood cases involving assisted reproduction, to reflect the marriage of people of the same sex.

Consent

32. In line with the principle set down in the Warnock Report[23], gametes and embryos cannot be treated as property. Their use in treatment and research is governed solely by the terms of the consent given by the gamete providers (including the providers of gametes used to create an embryo). This is why the 1990 Act did not and does not now contain the concept of presumed consent. Consent must be in writing and signed by the person giving it[24]. However, the legislation, while retaining these basic requirements, recognises that there are legitimate exceptions to this key principle:

- There will be occasions when a competent gamete provider cannot sign a consent form solely because of a physical disability. Amendments made by the 2008 Act now enable a disabled gamete provider to direct another person, in the presence of a witness, to complete and sign the consent form on his or her behalf[25].
- There may also be rare cases where it may be in the patient's interest to recover their gametes for storage, to preserve their chance to have children that are genetically their own, where they cannot give consent. Examples of this are a child about to undergo cancer treatment that might render them infertile but who is not yet competent to give consent to gamete recovery and storage, or an adult unconscious following an accident or serious illness, the treatment of which may impair that person's future fertility. In such cases, providing a clinician is of the opinion that the gamete provider will attain or recover competence, and other conditions set out in the 1990 Act are met, gametes can be recovered and stored without consent until such time as the gamete provider is able to determine what should happen to them.

  This exception applies solely to recovery and storage. Gametes may not be used without the written consent of the provider. If there is no expectation of future competence, gametes should not be recovered and stored[26].
- The consent of both the provider of the sperm and the provider of the egg used to create an embryo is required for the embryo to be stored and subsequently used in treatment or research. If one of the parties withdrew their consent, the embryo could not be used and, if in storage, had to be withdrawn and allowed to perish, irrespective of the other person's wishes. The 2008 Act amendments introduced a "cooling-off" period if one of the gamete providers' consent was withdrawn. Unless the provider was an egg or sperm donor, when the notice of withdrawal was received a one year waiting period was introduced.

  This allowed time for the clinic to notify the other party involved of the first party's intentions. If the second person agreed,

23 Report of the committee of inquiry into human fertilisation and embryology, chaired by Baroness (then Dame) Mary Warnock, published in July 1984. The committee was asked by Government to examine the social, ethical and legal implications of then recent developments in human assisted reproduction and potential developments in the future. Its recommendations formed the basis of the Human Fertilisation and Embryology Act 1990. The report was clear that there should be no right of ownership in relation to human embryos (and gametes used to create embryos). Any activities involving their use should only take place with the consent of the persons who provided the gametes, including the providers of gametes used to create embryos.

24 Paragraph 1(1) of Schedule 3 to the 1990 Act.

25 Paragraph 1(2) of Schedule 2 to the 1990 Act.

26 Paragraphs 8 and 9 of Schedule 2 to the 1990 Act.

the embryo was immediately allowed to perish. If the second person opposed the decision, the one year period allowed them time to see if an amicable solution to the future of the embryo could be reached or to seek legal advice. If at the end of the year there is still no agreement, and legal action is not on-going, the embryo will automatically be allowed to perish[27].

33. It was always the Government's expectation that such provisions would not be heavily used, although the Department of Health does not collect data on the level of usage, and would not wish to place such an administrative burden on clinics. The Government continues to believe that such provisions are necessary to ensure fairness for all and that patients' best interests can be taken into account during treatment at a time of serious injury or illness.

34. There are related provisions on the creation, use and storage of human admixed embryos for research purposes, where the embryos are to be created using tissue taken from a young person who has not attained age 18. In such cases, the embryos would be created to study specific, often rare, diseases. In these cases, the person having parental responsibility for the young person can consent to tissue being taken from that young person and for it to be used to create a human admixed embryo for use in research. There is a similar provision concerning the use of tissue from an adult lacking capacity.[28]

Disclosure of information

35. A substantial number of the provisions in the 1990 Act cover the disclosure of identifying information, which has a higher level of protection applicable to it than is applicable to many other types of health record. These were extensively revised by the 2008 Act.

36. The 2008 Act removed a prohibition that prevented people consenting to the disclosure of identifying information held on the HFEA's register of patients, treatments, donors and offspring, even where they understood the implications of the disclosure and were willing to allow the information to be released. Whatever the original rational for this prohibition, this now seemed an unnecessarily restriction[29]. The 1990 Act, however, retains the prohibition where disclosure could result in a link being made between a donor–conceived person and their gamete/embryo donor, to prevent the provisions controlling the release of such information being circumvented[30].

37. The provisions on the release of information about gamete and embryo donation have been extensively revised to allow donors to have more information about the use of their gametes or embryos and also to establish an opt-in register for donor-conceived people to register their wish to have information about genetic siblings who similarly register[31].

38. One of the most significant changes concerns the use of the data on the HFEA's register for research purposes. The register is probably the most comprehensive collection of such data in the world and, at the outset of work on the 2008 Act, the Government gave a commitment to see what could be done to make this information more readily available for use in research. The lifting of the prohibition on individuals consenting to the disclosure of identifying register data about themselves went some way to achieving this aim, however, some of the data on the register was up to 19 years old. The

27 Paragraphs 4(1) and 4A of Schedule 3 to the 1990 Act.

28 Paragraphs 12-22 of Schedule 3 to the 1990 Act.

29 Former section 33 of the 1990 Act.

30 Subsection 33A(2)(h) of the 1990 Act.

31 Sections 31ZA-31ZE of the 1990 Act.

new regulations[32] created a mechanism for researchers to seek access to information recorded on the register prior to October 2009, when the prohibition on consenting to disclosure of identifying information held on the HFEA's register was lifted, where it is impractical to obtain consent to the disclosure from the persons to whom the information relates. The Regulations also enable disclosure where the information relates to children.

39. For information recorded on the register since October 2009, disclosure has only been possible with the consent of the persons to whom the information relates, because of the lifting of the restriction on giving such consent. Patients are now asked to consider giving consent to their identifying information being used in research at the outset of their treatment. An informal assessment of the take up by HFEA indicated that, by far, patients are deciding not to allow their personal data to be used in research, even though efforts have been and continue to be made to encourage participation in research projects.

40. For the historic data, the Government envisaged that low-level use would be made of this procedure and this has proved to be the case. To date, six projects have been approved by the HFEA, which is the authority designated in the Regulations to adjudicate on applications for access to information under this scheme. Details of these projects are available on the HFEA's website.

41. The final information provision concerns gamete and embryo donation prior to the implementation of the 1990 Act in August 1991. A voluntary contact register was established in 2004, with Government funding, as a tool to enable pre-1991 gamete and embryo donors and people born as the result of such donations to make contact with each other, should both parties register a wish or agreement to do so. Since its establishment, the register has been maintained by a voluntary sector organisation but the 2008 Act introduced a provision to enable the HFEA to take over the operation of the register[33]. This option has not been exercised and the register continues to be operated by the voluntary sector[34].

Creation and use of human admixed embryos in research

42. The 2008 Act removed any uncertainty about whether the 1990 Act permitted the creation of human/animal hybrid embryos (correctly described as human admixed embryos) for use in research, applying a robust regulatory framework to their creation and use, including the 14 day/appearance of the primitive streak limitation on keeping embryos that is applicable to all human embryo research.

43. To date, the HFEA has licensed one project involving the creation of human admixed embryos that is being carried out at a leading stem cell research centre, although this was prior to the 2008 Act provisions coming into force. Although this is not a substantial area of research at this time, the HFEA continues to work closely with the Home Office, which regulates the use of animal material in research, to develop a cohesive policy on this and other matters where the interests of both regulators coincide.

32 The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010, S.I. 2010/995, made under section 33D of the 1990 Act.

33 Sections 31ZF and 31ZG of the 1990 Act.

34 The register, originally known as UK Donor Link, was operated by the voluntary organisation After Adoption Yorkshire and was maintained with funding from the Department of Health. Since 2012, the register, now called the Donor Conceived Register, has been maintained by the National Gamete Donation Trust as part of the National Gamete Donation Service, again with funding from the Department.

Views of the national regulator

44. The HFEA has advised that it is of the view that the 2008 Act has been successful in ensuring that the legislation in this area remains fit for purpose. Examples of this are the amendment to the welfare of the child assessment to include the need of the child for supportive parenting, the provisions that allow the HFEA to disclose, for research purposes, identifying information held on its register, and the scope for HFEA members to delegate functions to HFEA staff.

45. In the field of assisted reproduction and embryology there is very close interaction between medicine, science and ethics. This means that new and enhanced treatment services and research, and ethical and societal views, are constantly developing. In this environment there are limits on the extent to which primary legislation can foresee and prescribe for every eventuality, and the appropriateness of it attempting to do so.

46. The legislation, therefore, provides the HFEA with some degree of flexibility and scope for interpretation, which it has applied. An example of this concerns legal fatherhood in cases of surrogacy. In this instance the HFEA has interpreted the legislation and has provided guidance to say that a man who provides the sperm to be used to inseminate a surrogate who has no husband or partner should be recognised as the legal father of the child at outset, without the need to obtain a parental order.

Conclusion

47. The Government considers that the 2008 Act has met its aim of ensuring that the legislation in the area of assisted reproduction is fit for purpose in the 21st Century. The 2008 Act has created mechanisms to enable legislation to take account of developments in treatment services and research whilst ensuring that they continue to be delivered within a safe and ethical environment.

Department of Health
March 2014

Annex A

COMMENCEMENT DATES FOR PROVISIONS OF THE 2008 ACT

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Part 1: Amendments of the Human Fertilisation and Embryology Act 1990			
Section 1 *Meaning of "embryo and "gamete"*	Section 1 *Meaning of "embryo, "gamete" and associated expressions*	1 October 2009	2009/2232[(1)]
Section 2 *Meaning of "nuclear DNA"*	Section 2 *Other terms*	1 October 2009	2009/2232
Section 3 *Prohibitions in connection with embryos*	Section 3 *Prohibitions in connection with embryos* Section 3ZA *Permitted eggs, permitted sperm and permitted embryos*	1 October 2009	2009/2232
Section 4 *Prohibitions in connection with genetic material not of human origin*	Section 4 *Prohibitions in connection with gametes* Section 4A *Prohibitions in connection with genetic material not of human origin*	1 October 2009	2009/2232

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 5 *Membership of the Authority: disqualification and tenure*	Schedule 1 *The Authority: supplementary provisions*	1 October 2009	2009/2232
Section 6 *Additional general functions of Authority*	Section 8 *General functions of the Authority*	1 October 2009	2009/2232
Section 7 *Duties in relation to carrying out functions*	Section 8ZA *Duties in relation to carrying out its function*	1 October 2009	2009/2232
Section 8 (partially) *Power to contract out functions etc.* i. Commencement of section 8B of the 1990 Act. ii. Commencement of section 8C of the 1990 Act, with the exception of subsection (7) related to inspection, entry, search and seizure and the keeping of embryos by a member or employee of the HFEA in pursuance of their function on behalf of the HFEA. iii. Commencement of Section 8D for the purposes of establishing committees to carry out HFEA's function on reconsideration of licensing decisions.	Section 8B *Agency arrangements and provision of services* Section 8C *Contracting out functions of the Authority* Section 8D *Disclosure of information where function of the Authority exercised by others*	6 April 2009	2009/479[(2)]

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 8 (fully)		1 October 2009	2009/2232
Section 9 *Power to assist other public authorities*	Section 8E *Power to assist other public authorities*	1 October 2009	2009/2232
Section 10 *Power to delegate and establish committees*	Section 9A *Power to delegate and establish committees*	1 October 2009	2009/2232
Section 11 *Activities that may be licensed*	Section 11 *Licences for treatment, storage and research* Schedule 2 *Activities for which licences may be granted*	1 October 2009	2009/2232
Section 12 *General conditions of licences*	Section 12 *General conditions*	1 October 2009	2009/2232
Section 13 *Consent to use or storage of gametes, embryos, human admixed embryos etc.*	Schedule 3 *Consent to use or storage of gametes, embryos or human admixed embryos.*	1 October 2009	2009/2232
Section 14 (partially) *Conditions of licences for treatment* i. Commences new licence conditions related to the provision of information, counselling and notifications to couples undergoing treatment at HFEA licensed clinics.	Section 13 *Conditions of licences for treatment* Schedule 3ZA *Supplementary licence conditions: human application*	6 April 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 14 (fully)		1 October 2009	2009/2232
Section 15 (partially) *Conditions of storage licences* i. Commences amendment on embryo storage limit (where extended storage not applicable for medical reasons) from five to ten years. ii. Commences new regulation making powers on extended storage periods.	Section 14 *Conditions of storage licences*	6 April 2009	2009/479
Section 15 (fully)		1 October 2009	2009/2232
Section 16 *Grant of licences*	Section 16 *Grant of licences*	1 October 2009	2009/2232
Section 17 *The person responsible*	Section 17 *The person responsible*	1 October 2009	2009/2232
Section 18 *Revocation and variation of licence*	Section 18 *Revocation of licence* Section 18A *Variation of licence*	1 October 2009	2009/2232

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 19 (partially) *Procedure for refusal, variation or revocation of licence* i. Commences regulation making powers in relation to revocation and variation of licences.	Section 19 *Procedures in relation to licensing decisions* Section 19A *Notification of licensing decisions* Section 19B *Applications under the Act*	6 April 2009	2009/479
Section 19 (fully)		1 October 2009	2009/2232
Section 20 *Power to suspend licence*	Section 19C *Power to suspend licence*	1 October 2009	2009/2232
Section 21 (partially) *Reconsideration and appeals* i. Commences regulation making powers on the appeals committee and procedure on reconsideration.	Section 20 *Right to reconsideration of licensing decision* Section 20A *Appeals committee* Section 20B *Procedure on reconsideration*	6 April 2009	2009/479
Section 21 (fully)		1 October 2009	2009/2232
Section 22 *Directions*	Section 24 *Directions as to particular matters*	1 October 2009	2009/2232
Section 23 *Code of practice*	Section 25 *Code of practice*	1 October 2009	2009/2232

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 24 (partially) *Register of information* i. Commences regulation making powers in relation to requests for information as to genetic parentage etc.	Section 31 *Register of information* Section 31ZA *Request for information as to genetic parentage etc.* Section 31ZB *Request for information as to intended spouse etc.* Section 31ZC *Power of Authority to inform donor of request for information* Section 31ZD *Provision to donor of information about resulting children* Section 31ZE *Provision of information about donor-conceived genetic siblings* Section 31ZF *Power of Authority to keep voluntary contact register* Section 31ZG *Financial assistance for person setting up or keeping voluntary contact register*	6 April 2009	2009/479
Section 24 (fully)		1 October 2009	2009/2232

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 25 (partially) *Restrictions on disclosure of information* i. Commences regulation making powers on the disclosure of information for research purposes.	Section 33A *Disclosure of information* Section 33B *Consent required to authorise certain disclosures* Section 33C *Power to provide for additional exceptions to section 33A(1)* Section 33D *Disclosure for the purposes of medical or other research*	6 April 2009	2009/479
Section 25 (partially) i. Commences section, with the exception of a new exception on the disclosure of identifying information in proceedings relating to an application for a parental order.		1 October 2009	2009/2232
Section 25 (fully)		6 April 2010	2010/987[(3)]
Section 26 (partially) *Mitochondrial donation* i. Commences section, with the exception of the meaning of "relevant provisions" in relation to parental orders.	Section 35A *Mitochondrial donation*	1 October 2009	2009/2232
Section 26 (fully)		6 April 2010	2010/987

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 27 *Fees*	Section 35B *Fees*	1 October 2009	2009/2232
Section 28 *Inspection, entry, search and seizure*	Section 38A *Inspection, entry, search and seizure* Schedule 3B *Inspection, entry, search and seizure*	1 October 2009	2009/2232
Section 29 *Offences under the 1990 Act*	Section 41 *Offences*	1 October 2009	2009/2232
Section 30 *Regulations under the 1990 Act*	Section 45 *Regulations*	6 April 2009	2009/479
Section 31 *Power to make consequential provision*	Section 45A *Power to make consequential provision*	1 October 2009	2009/2232
Section 32 *Orders under the 1990 Act*	Section 45B *Orders*	1 October 2009	2009/2232
Part 2: Parenthood in cases involving assisted reproduction			
Section 33 *Meaning of "Mother"*		6 April 2009	2009/479
Section 34 *Application of sections 35-47*		6 April 2009	2009/479
Section 35 *Woman married to a man at time of treatment*		6 April 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 36 *Treatment provided to woman where agreed fatherhood conditions apply*		6 April 2009	2009/479
Section 37 *The agreed fatherhood conditions*		6 April 2009	2009/479
Section 38 *Further provision relating to sections 35 and 36*		6 April 2009	2009/479
Section 39 *Use of sperm, or transfer of embryo, after death of man providing sperm*		6 April 2009	2009/479
Section 40 *Embryo transferred after death of husband etc. who did not provide sperm*		6 April 2009	2009/479
Section 41 *Persons not treated as father*		6 April 2009	2009/479
Section 42 *Woman in civil partnership or marriage to a woman at time of treatment*		6 April 2009	2009/479
Section 43 *Treatment provided to woman who agrees that second woman to be parent*		6 April 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 44 *The agreed female parenthood conditions*		6 April 2009	2009/479
Section 45 *Further provision relating to sections 42 and 43*		6 April 2009	2009/479
Section 46 *Embryo transferred after death of civil partner or wife or intended female parent*		6 April 2009	2009/479
Section 47 *Woman not to be other parent merely because of egg donation*		6 April 2009	2009/479
Section 48 *Effect of sections 33-47*		6 April 2009	2009/479
Section 49 *Meaning of references to parties to a marriage*		6 April 2009	2009/479
Section 50 *Meaning of references to parties to a civil partnership*		6 April 2009	2009/479
Section 51 *Meaning of "relevant register of births"*		6 April 2009	2009/479
Section 52 *Late election by mother with consent of Registrar General*		6 April 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 53 *Interpretation of references to father etc.*		6 April 2009	2009/479
Section 54 (partially) *Parental orders* i. Commences regulation making power related to section 55		1 October 2009	2009/2232
Section 54 (fully)		6 April 2010	2010/987
Section 55 *Parental orders: supplementary provisions*		1 October 2009	2009/2232
Section 56 (partially) *Amendments relating to parenthood in cases involving assisted reproduction* i. Commences amendment related to Schedule 6.		6 April 2009	2009/479
Section 56 (partially)		1 October 2009	2009/2232
Section 56 (fully)		6 April 2010	2010/987
Section 57 (partially) *Repeals and transitional provision relating to Part 2* i. Commences repeal and transitional provisions on the status of children related to sections 33-48 and the equivalent (now repealed) sections on parenthood (27-29) contained in the 1990 Act.		6 April 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 57 (fully)		6 April 2010	2010/987
Section 58 *Interpretation of Part 2*		6 April 2009	2009/479
Part 3: Miscellaneous and general			
Section 59 *Surrogacy arrangements*		1 October 2009	2009/2232
Section 60 *Exclusion of embryos from definition of "organism" in Part 6 of the EPA 1990*		1 October 2009	2009/2232
Sections 61-64[4]		–	–
Section 65 (partially) *Minor and consequential amendments* i. Commences statutory provisions to apply the Statutory Instruments Act 1946 to the 1990 Act.		6 April 2009	2009/479
Section 65 (fully)		1 October 2009	2009/2232
Section 66 (partially) *Repeals and revocations* i. Commences provisions to repeal the 5 year storage limit in the 1990 Act.		6 April 2009	2009/479
Section 66 (partially) i. Commences provisions to repeal various provisions relating to parenthood.		1 September 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Section 66 (fully)		6 April 2010	2010/987
Sections 67- 69[5]		–	–
Schedule 1 *Amendments to Schedule 1 to the 1990 Act relating to membership of the Authority*	Schedule 1 *The Authority: supplementary provisions*	1 October 2009	2009/2232
Schedule 2 *Activities that may be licensed under the 1990 Act*	Schedule 2 *Activities for which licences may be granted*	1 October 2009	2009/2232
Schedule 3 *Consent to use or storage of gametes, embryos or human admixed embryos etc.*	Schedule 3 *Consent to use or storage of gametes, embryos or human admixed embryos.*	1 October 2009	2009/2232
Schedule 4 *Schedule inserted in the 1990 Act as Schedule 3ZA*	Schedule 3ZA *Circumstances in which offer of counselling required as condition of licence for treatment*	6 April 2009	2009/479
Schedule 5 *Schedule inserted in the 1990 Act as Schedule 3B*	Schedule 3B *Inspection, entry, search and seizure*	1 October 2009	2009/2232
Schedule 6 (partially) *Amendments relating to parenthood in cases involving assisted reproduction* i. Commences amendments to other Acts relating to parenthood.		6 April 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Schedule 6 (partially) i. Commences amendments to other Acts relating to parenthood.		1 September 2009	2009/479[6]
Schedule 6 (fully)		6 April 2010	2010/987
Schedule 7 (partially) *Minor and consequential amendments* i. Linked to partial commencement of section 65.		6 April 2009	2009/479
Schedule 7 (fully)		1 October 2009	2009/2232
Schedule 8 (partially) *Repeals and revocations* i. Commences repeal of words in 1990 Act relating to 5 year statutory storage period.		6 April 2009	2009/479
Schedule 8 (partially) i. Commences repeal of section 1(4) of the Family Law Act (Northern Ireland) 2001 and Article 7 of the Children (Northern Ireland) Order 1995 and parts of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003.		1 September 2009	2009/479

Section in 2008 Act	Equivalent section in 1990 Act, where appropriate	Date of commencement	Statutory Instrument no.
Schedule 8 (partially) i Commences Schedule, with exception of the repeal of section 30 of the 1990 Act (parental orders in favour of gamete donors).		1 October 2009	2009/2232
Schedule 8 (fully)		6 April 2010	2010/987

Notes

(1) S.I. 2009/2232: The Human Fertilisation and Embryology Act 2008 (Commencement No.2 and Transitional Provision) and (Commencement No.1 Amendment) Order 2009.

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

(3) S.I. 2010/987: The Human Fertilisations and Embryology Act 2008 (Commencement No.3) Order 2010.

(4) Sections not covered by commencement orders so came into force on the date the 2008 Act was passed (13 November 2008): section 61 – Orders and regulations: general provisions, section 62 – Orders and regulations: parliamentary control, section 63 – Meaning of "the 1990 Act", section 64 – Power to make consequential and transitional provision etc. (see section 68 of the 2008 Act).

(5) Sections not covered by commencement orders so came into force on the date the 2008 Act was passed (13 November 2008): section 67 – Extent, section 68 – Commencement, section 69 – Short title (see section 68 of the 2008 Act).

(6) Article 6(2) of S.I. 2009/479, which partially commenced provisions in Schedule 6, was amended by article 3 of S.I. 2009/2232.

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