

Review of the Human Fertilisation and Embryology Act : proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos) / Department of Health.

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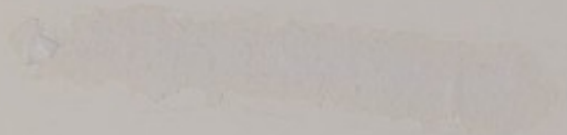
Review of the Human Fertilisation and Embryology Act

Proposals for revised legislation (including
establishment of the Regulatory Authority
for Tissue and Embryos)

Presented to Parliament by the
Secretary of State for Health

by Command of Her Majesty

December 2006



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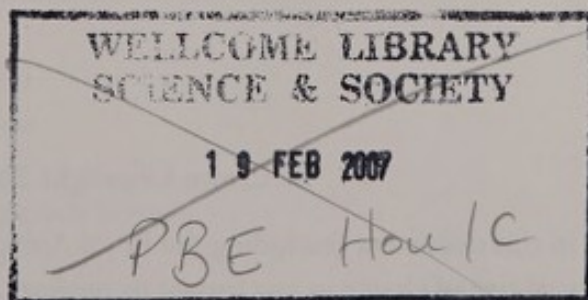
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for Tissue and Embryos)

Department of Health 2006





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Foreword



The United Kingdom is at the forefront of developments in human reproductive technologies. This country can be justly proud of its record not only in pioneering new techniques for alleviating infertility or conducting research into serious diseases, but also in their effective regulatory oversight. Medical and scientific breakthroughs, and public confidence in them based on clear boundaries and controls, go hand in hand in this area.

The Department of Health undertook a public consultation exercise over the summer and autumn of 2005 on possible changes to update the law and regulation relating to human reproductive technologies. This was part of a review intended to ensure that the law remained fit for purpose in the early 21st Century. The consultation built on a succession of reports, reviews, studies and surveys taking account of the rise of new technologies, international developments, and possible changes in public attitudes since the drawing up of the Human Fertilisation and Embryology Act 1990. A summary of the consultation comments received was published in March 2006.

The Government has carefully considered a full range of viewpoints, suggestions and proposals, many of which have fundamental social, legal and ethical aspects. In drawing up our proposals, in an area where there is unlikely to be consensus, we have attempted to balance the competing claims of reproductive liberty and responsibility, patient safety, child welfare, professional autonomy and public accountability. The overarching aim is to pursue the common good through a system broadly acceptable to society. We hope to have presented here a forward-looking regulatory scheme that is targeted and proportionate, as well as intelligible and enforceable.

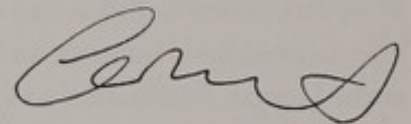
Like the House of Commons Science and Technology Committee, which published its own review of the law in 2005, we have taken the most basic components of the existing legal scheme as bedrock. These include the special status ascribed to the human embryo outside the body, coupled with the permissibility of embryo research within defined limits. We have also consistently made clear that we do not intend to remove the firmly established ban on human reproductive cloning, nor to reverse the removal of donor anonymity.

We also propose to retain the principle of active monitoring and regulation by an independent body, based on a scheme of licensing, and ultimately backed by criminal penalties. We believe that this model remains both appropriate and effective. More details of our intention to create the Regulatory Authority for Tissue and Embryos (RATE),

announced following a wide-ranging review of the Department of Health's arm's length bodies, are included here.

The creation of RATE, replacing the Human Fertilisation and Embryology Authority and the Human Tissue Authority, gives us the opportunity to establish a single competent authority acting as the regulator under the European Union Blood, and Tissues and Cells Directives. It allows us to have a single source of authoritative guidance on all issues relating to the use of human tissue of all kinds, and to secure the application of good regulatory practice and common principles in these related areas.

This paper sets out the detailed policy proposals that the Government will present to Parliament, which, if Parliament agrees, will form part of revised legislation. We intend that these proposed changes will first be considered in draft form, as a Bill published for pre-legislative scrutiny. I am looking forward to a full, open and stimulating debate.



Caroline Flint MP
Minister of State for Public Health
December 2006

1. Introduction

- 1.1 The development and use of human reproductive technologies continue to raise a range of complex and profound social, legal and ethical questions. Addressing those issues and questions goes to the very heart of our existence as individuals, families, and society. Sincerely held views and opinions differ widely, but also share the widespread desire for *some* principles, barriers or limits to govern behaviour in this area. The Human Fertilisation and Embryology Act 1990 (the HFE Act) reflected an underlying will to find common ground in setting a framework broadly acceptable to society, as agreed by Parliament.
- 1.2 In deciding to review the law and regulation in this area, the Government recognised that the HFE Act had worked well and largely continued to do so, enabling science and medicine to flourish within agreed parameters and promoting public confidence. The Government's aim in undertaking its review was to ensure that the law and regulation remained effective and fit for purpose given the pace of scientific developments and public attitudes associated with them.
- 1.3 The Government decided a review was timely and desirable in light of:
- the development of new procedures and technologies in assisted reproduction
 - international developments in the standards that clinics have to meet
 - possible changes in public perceptions and attitudes on complex ethical issues
 - the need to ensure the continued effectiveness of regulation, to reduce uncertainty and the scope for legal challenges.
- 1.4 This document details the outcome of that review, and presents the Government's proposals for revised legislation that, in due course, will be presented to Parliament in the form of a published draft Bill. These include the Government's commitment to set up the Regulatory Authority for Tissue and Embryos (RATE), announced in July 2004 as part of a wider programme to improve efficiency, reduce the burden on the frontline and free-up more resources for the delivery of services to patients. RATE will replace the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) with a single regulator with responsibilities across the range of human tissues, cells and blood.

- 1.5 The Government has taken a deliberative and consultative approach in reviewing the existing legislation and drawing up proposals for revisions. This has included taking account of the recommendations of the House of Commons Science and Technology Committee's report *Human Reproductive Technologies and the Law*, published in March 2005 following a yearlong inquiry. A wide range of other reviews (including several from Parliamentary select committees), written evidence and surveys, as well as Government-commissioned reports have been assimilated, culminating in the Department of Health's public consultation exercise in the latter part of 2005. This is an area of science and medicine that gives rise to a diversity of reactions, including considerable unease or anxiety in the public mind, and it was important to take all of these sources and data into account.
- 1.6 This approach also recognised the fact that the law as it currently stands is the result of an extensive process of consultation, discussion and reflection over a period stretching back at least to 1978 and the first birth of a child conceived using *in vitro* fertilisation (IVF). The advent of IVF enabled, for the first time, human embryos to be created outside the body and thereby opened up new possibilities to observe, select, test, and potentially to control and modify the very earliest stages of human development. It also brought new hope of alleviating infertility to many thousands of couples and, through advances in cellular research, increasingly the promise of treatments for serious diseases.
- 1.7 Statute law and associated regulatory structures have been built up over the past two decades, largely based on the findings of a Committee of Inquiry chaired by Dame (now Baroness) Mary Warnock, followed subsequently by public consultation and vigorous parliamentary debate. The Warnock Committee concluded that there was an urgent need for a scheme of active monitoring and regulation in this area. At the centre of the scheme was a statutory authority independent of Government and the relevant professions, with both executive and advisory functions, including the licensing of programmes of IVF treatment or the use of donated sperm, eggs or embryos. The human embryo outside the body was to be ascribed a special status that gave some protection in law but also recognised the benefits accruing from research using embryos within limits.
- 1.8 The Government has concluded that the foundations of the current law remain sound, and provide an effective and appropriate model of regulation for the development and use of human reproductive technologies. This echoes the findings of the recent inquiry by the House of Commons Science and Technology Committee, which similarly concluded that the approach taken to the status of the human embryo remained appropriate.

- 1.9 The Committee made a wide range of recommendations in an extensive report, the broad thrust of which was aimed at securing the maximum freedom of action for individual adults in the absence of demonstrable harms. Many of those recommendations became issues for the Government's own review and were included in its public consultation. At the same time, the Government made clear that it did not intend to reopen debate on those fundamental aspects of the law that are widely accepted in our society or which have been recently debated and conclusively resolved in Parliament. These include the creation and use of embryos for research, the prohibition of human reproductive cloning, and the removal of donor anonymity.
- 1.10 A total of 535 formal responses to the consultation were received. These comprised submissions from around 100 stakeholder groups and organisations, and responses from a wide range of individual professionals, patients and members of the public. Responses were received from:
- fertility clinics
 - professionals, including embryologists, geneticists and counsellors
 - the Royal Colleges and other representatives of the medical professions
 - representatives of patients, donors, and donor-conceived persons
 - churches and faith communities
 - ethicists
 - social workers
 - representatives and members of the scientific research community
 - individual members of the public.
- 1.11 March 2006 saw the publication of an independently commissioned summary of the responses. This was designed to draw out the landscape of arguments being presented and to place contrasting views side by side. The responses covered a wide diversity of opinions and arguments. However, it was clear that responses generally favoured measures such as a ban on sex selection of offspring for non-medical reasons, retention of a 'welfare of the child' consideration in some form in decisions to provide fertility treatments, and controls on the potential use of so-called "artificial gametes" in the future. Respondents were generally less convinced of the need to make changes to the scope of permissible embryo research.
- 1.12 Society's collective and considered opinion is the ultimate arbiter of the controls to be applied to the development and use of human reproductive technologies. It will be for Parliament to weigh and consider the proposals presented in this document in the

form of draft legislation. The Government believes it is important that the legal and regulatory parameters in this area are publicly reviewed, removed where no longer appropriate, and reinforced or replaced where necessary. This document is part of that process:

- it sets out the Government's proposals for changes to the law, setting them in the context of other recent or proposed changes
- proposals for the structure and functioning of RATE are included
- a summary table of the proposed changes is provided for ease of reference
- a partial regulatory impact assessment is included that compares the Government's proposed approach against 'do nothing' and deregulatory options
- finally, there are sources of further reading, details of other related legislation, and relevant contact details at the end of the document.

2. Proposals for revised legislation

- 2.1 This document details the Government's proposals for changes to **the Human Fertilisation and Embryology Act (the HFE Act)**¹, including establishment of the **Regulatory Authority for Tissue and Embryos (RATE)**, which will be presented to Parliament in draft form. The changes proposed are concerned with *what the law requires*, including the legally defined aspects of the regulatory structure, and do not directly address the day to day workings and detailed guidance of the regulator, or the funding and provision of healthcare by the National Health Service.

Aims

- 2.2 Underlying the proposals set out below, is the principle that there remains an ongoing need for active regulation and monitoring of the development and use of human reproductive technologies, within legally defined boundaries, in response to public concerns. In proposing revisions to the existing legal and regulatory framework, the Government's principal aims are:
- to ensure that legitimate medical and scientific applications of human reproductive technologies can continue to flourish
 - to promote public confidence in the development and use of human reproductive technologies through effective regulatory controls applicable to them
 - to secure that regulatory controls accord with better regulation principles and encourage best regulatory practice.

Territorial extent

- 2.3 If approved by Parliament, the proposed changes to the HFE Act will apply throughout the United Kingdom, as that Act deals with matters reserved to the UK Parliament in Westminster. The remit of RATE will cover the whole of the UK for those matters formerly within the remit of the HFEA, and will cover England, Wales and Northern Ireland for those matters formerly within the remit of the Human Tissue Authority (reflecting the territorial application of the Human Tissue Act 2004). RATE will, however, be able to assist the relevant authorities in Scotland in relation to human tissues if invited to do so by Scottish Ministers.

1 Whereas the HFE Act made amendments to the Abortion Act 1967, this review has not considered the issue of abortion, and the Government does not intend to make any changes to the law on abortion.

The model of regulation

- 2.4 The Government proposes that **the current model of regulation, whereby Parliament sets the prohibitions and parameters within which a statutory authority licenses activities, should continue.** This model has worked well to date and the Government believes that it remains appropriate given the nature of the issues under consideration. Ultimately, this model includes criminal sanctions that can be applied to persons who flout the law. At the same time, the Government recognises that several techniques for the alleviation of infertility have become commonplace – with, for example, over eight thousand births per annum in the UK resulting from IVF – and that this should be reflected in the extent and detail of day to day regulatory requirements.
- 2.5 The nature of the area of human reproductive technologies – as an inherently fast-moving area of science and medicine – means that regulatory controls need to be responsive to technological advances, and to keep pace with significant changes in public attitudes. This requires that the law and regulatory structures are sufficiently flexible to remain effective, whilst at the same time ensuring the regulator's accountability to the public and Parliament.
- 2.6 The current model includes powers for Parliament to impose further controls using secondary legislation (regulations), and in certain areas to extend or vary existing controls. It also includes requirements on the Secretary of State and the regulator to account to Parliament for activities and expenditure. (The operation and accountability of RATE is discussed further in section 3). Issues that fall outside of the scheme of regulation, or which require a substantial variation of legal controls would require new primary legislation and therefore a fresh mandate from Parliament.
- 2.7 The law must be practicable and enforceable, and must also take account of the United Kingdom's relevant international obligations. These proposals assume implementation of Directive 2004/23/EC of the European Parliament and the Council of the European Union on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (the EU Tissue Directive). Secondary legislation to transpose the Directive into domestic law from April 2007 will be laid before Parliament shortly.

Embryos and gametes

- 2.8 The HFE Act applies principally to activities involving human gametes (generally meaning sperm and eggs) and embryos. There are a small number of outright prohibitions (such as placing a human embryo in an animal), and the requirement

to hold a licence from the HFEA in order to be able, for example, to create embryos outside the body, or use donated gametes in providing treatment services.

- 2.9** The Government continues to accept that **activities involving the creation, keeping or use of embryos outside the body, or the use of donated gametes, should continue to be subject to licensing by an independent regulator.** This requirement follows in part from recognition of a special status for the human embryo – that it should be afforded some protection in law whilst not precluding assisted conception or some forms of research – and also the fundamental ethical, social and legal concerns associated with the donation of gametes and embryos.

The meaning of “embryo”

- 2.10** The legal meanings of the terms “embryo” and “gamete” are crucial in determining the scope of regulation and therefore whether a proposed activity requires a licence. At present, the HFE Act includes references to the process of fertilisation whereby embryos are created, by which it means the union of sperm and egg. Technology has, however, moved on and resulted in a multitude of possible techniques for the creation of embryos other than via fertilisation in the traditional sense. For example, embryos have been created for research into serious diseases by the process of cell nuclear replacement (involving replacing the nucleus of an egg with a nucleus taken from another cell). The wording of the existing law has been challenged on the basis that it did not appear to cover embryos created by these novel processes.
- 2.11** The Government intends that **all human embryos outside the body, regardless of the manner of their creation, will be within the scope of regulation.** Like the House of Commons Science and Technology Committee, the Government recognises the inherent difficulty of framing definitions based on either the means of creation or the developmental potential of the entity in question. The proposed approach is to define the forms of embryo that may be placed in a woman (recognising that the Human Reproductive Cloning Act 2001 already makes it illegal to place in a woman an embryo created otherwise than by fertilisation), and to ensure that all human embryos created for research purposes are subject to licensing.

Eggs in the process of fertilisation

- 2.12** Under the HFE Act as it stands, eggs *in the process of* fertilisation are considered to be embryos for the purposes of regulation. This contrasts with alternative approaches that would specify a later stage of development as marking the first appearance of an embryo proper – for example when the fertilised egg divides to form two cells, which generally occurs at around 36 hours. The Government has rejected this alternative approach and intends that the **law will continue to treat ‘eggs in the process**

of fertilisation' in the same way as embryos, and this will also apply to eggs undergoing other processes of embryo creation. The purpose is to avoid any doubt about whether fertilised eggs are covered by regulation, and to extend this principle to take account of new technologies. Determining the precise point from which the requirement for a licence applies will also, as above, require practical guidance from the regulator.

The meaning of "gamete"

- 2.13 The HFE Act does not, as such, define "gametes", "eggs" or "sperm" other than to say that, unless otherwise stated, they refer to human gametes, eggs or sperm. In the same way that technological advances have cast doubt on the meaning of "embryo" within the Act, so future developments in the creation of so-called "artificial" gametes – cells capable of performing the same functions as naturally produced eggs and sperm – or gametes that have in some way been altered or modified, may similarly cast doubt on the extent to which regulation applies. The Government intends to ensure that the law will apply to all these cells, and proposes additional controls on the use of artificial gametes (described under the heading below).
- 2.14 Establishment of RATE will bring together the licensing roles of the HFEA and the Human Tissue Authority (HTA), as modified by implementation of the EU Tissue Directive. One effect of this will be to create a single authority responsible for the storage of gametes, and of ovarian and testicular tissue – which may contain gametes or their precursor cells at varying stages of development. It is intended that this will help avoid any perceived overlap of regulatory structures or inconsistency in the requirements relating to, for example, different samples of ovarian tissue.

Artificial gametes

- 2.15 The development of artificial gametes – which may in future be developed from other non-gamete cells – would, in theory, enable the alleviation of infertility problems for persons in certain circumstances, such as where a man is unable to produce his own sperm. This development would also raise profound new possibilities such as the possible creation of a child by combining the genetic material of two women. The Government consulted on introducing a prohibition on the use of artificial gametes in assisted reproduction treatment on both safety and ethical grounds, and this was well supported by the responses received. **The Government proposes a ban on the use of non-naturally occurring gametes in assisted reproduction treatment.** In practice, this will mean that only gametes originating in the testes or ovaries may be used in treatment. This effect in principle will be extended to gametes used for, for example, artificial insemination.

- 2.16 The Government has considered whether such a ban on the use of artificial gametes should be capable of being removed through secondary legislation (that is by a regulation-making power). This would provide a ready mechanism to alter the law if safety concerns were allayed in future. The Government has decided, on balance, not to recommend such a power, proposing instead that this would be a matter requiring primary legislation.

Fresh gametes, and internet supply services

- 2.17 At present, the HFE Act regulates the storage of gametes, and the use of donated gametes in treatment services. It does not therefore regulate the use of a couple's own gametes in fertility treatments that do not involve either storage of gametes or the creation of an embryo outside the body. These will, however, be brought within the scope of regulation via implementation of the EU Tissue Directive.
- 2.18 Also, the law as currently worded does not apply to certain internet-based businesses that make arrangements for the supply of sperm for private self-insemination, because no treatment services are being provided. This activity will also be brought within the scope of regulation via the Directive's transposition into domestic law.
- 2.19 Implementation of the Directive will introduce European Union-wide standards of quality and safety to tissue and cells including gametes. Revised legislation will ensure that consistent standards and requirements are applied to all the licensable activities within RATE's remit – such as requirements for the provision of appropriate information to patients, and the legal status of gamete donors.

Welfare of the child and the assessment of those seeking treatment

- 2.20 Taking account of "the welfare of the child" is a mandatory condition of all licences to provide fertility treatments. Section 13(5) of the Act states that:

"a woman shall not be provided with treatment services unless account has been taken of the welfare of the child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth".

- 2.21 The regulator is legally obliged to give guidance to treatment providers on how to carry out this duty in practice, and in the past this has involved making relatively extensive enquiries about the prospective patients' circumstances. More recently, following a consultation exercise undertaken in 2005², the HFEA has revised its

2 *Tomorrow's Children*. A consultation on guidance to licensed fertility clinics on taking into account the welfare of children to be born of assisted conception treatment. HFEA, January 2005.

guidance to clinics in order to focus on the likelihood of serious harm, with a general presumption in favour of providing treatment for patients who seek it.

- 2.22 The Department of Health's consultation considered a range of issues about this part of the Act including whether it should remain a legal requirement, whether it should address solely medical matters, and whether it was appropriate to refer to a need for a father. The House of Commons Science and Technology Committee had recommended that section 13(5) should be abolished in its current form, largely on the grounds that persons able to conceive naturally, or persons receiving non-licensable fertility treatments, do not face similar checks.
- 2.23 **However, the Government believes that the presence of a "welfare of the child" section in the law remains valuable and proposes to retain a duty for treatment centres to consider the welfare of the child who may be born as a result of treatment, or any other child who may be affected.** The Government recognises that, in order to be proportionate, this obligation must strike a balance between ensuring that treatment providers do not abrogate the responsibilities that go together with their role in the creation of a new life, and being practicable and appropriate to their knowledge and skills.
- 2.24 Retention of a duty to consider the welfare of the child was well supported by responses to the Government's consultation, including some from representatives of the medical profession. Clinicians expect to consider a range of factors relating to patients' circumstances as a matter of 'good medical practice', and guidance from the regulator will continue to encourage consistent good practice amongst professionals.
- 2.25 Responses to the Government's consultation from individual members of the public generally favoured retention of a reference to the child's need for a father, as part of the consideration of the welfare of the child. Many thought that the legislation should be revised to refer to a need for both a mother and a father. The Government has carefully considered this matter, and in particular has taken into account considerations of the proper role of the State, and of clinicians, in seeking to determine family forms via controls on access to medically-assisted conception, particularly in the light of more recent enactments such as the law relating to civil partnerships.
- 2.26 **On balance, the Government has decided to propose that the reference to the need for a father (in consideration of the welfare of the child) should be removed from the Act.** The Government is not convinced that the retention of this provision could be justified in terms of evidence of harm, particularly when weighed against the potential harms arising from the consequences of encouraging some women who wish

to conceive to make private arrangements for insemination rather than use licensed treatment services.

Licence conditions on the use, storage and donation of gametes and embryos

- 2.27** The HFE Act imposes a number of mandatory conditions on licences granted by the regulator. These include requirements such as written consent for certain procedures, the offering of a suitable opportunity to receive counselling, time limits on the periods for which gametes and embryos may be stored, and controls on payments for the supply of gametes or embryos.
- 2.28** The mandatory requirements for written consent apply, in summary, to the creation and subsequent use of embryos, to the donation of gametes, and to the storage of gametes or embryos. The Government has considered whether these requirements remain an appropriate matter for the law, and has concluded that they provide a clear and valuable protection of the wishes of patients and donors. The Government does not intend, however, to extend the requirement for written consent to cover the use of a couple's own gametes in treatments to be brought within the scope of regulation via implementation of the EU Tissue Directive (but which do not involve embryos outside the body, or the storage or donation of gametes).
- 2.29** The Act also makes it a condition of all licences that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions from the HFEA. The Government does not intend to make proposals altering this basic position. The regulator will also be the 'competent authority' responsible for overseeing compliance with the requirements of the EU Tissue Directive, when transposed into domestic law. The Directive includes a statement of principles governing tissue and cell donation. Article 12 says that Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells but donors may receive compensation.

Storage of gametes from persons lacking capacity

- 2.30** The current requirement is that the gamete provider must give written consent for the storage of his or her gametes. This means that it is not possible to store a person's gametes where they are unable to consent, even where storage may be in the best interests of that person. This scenario may occur where a person is incapacitated through illness or injury and thus unable to provide written consent, but is likely to regain capacity at a later date, and there is a need to store gametes in order to preserve that person's capacity to reproduce. Similar scenarios could arise with children who have not yet developed capacity to give the required consent. These matters were

considered in some depth in a Department of Health-funded review led by Professor Sheila McLean of the School of Law, University of Glasgow, which reported in 1998³.

- 2.31 The Government accepted, in response to Professor McLean's report, that the law should be changed, when Parliamentary time allowed, to enable the storage of gametes without written consent in certain limited circumstances. **The Government therefore proposes to amend the law to enable the storage of gametes from persons lacking capacity where the gametes have been lawfully removed in the best interests of that person, without written consent, where medical opinion indicates that the person is likely to gain/ regain capacity.** The purpose would be to preserve the person's reproductive capacity, and any subsequent use of the gametes would still require that person's consent.
- 2.32 The law will also clearly allow a person who is physically unable to sign a consent form (for example, due to spinal injury) to direct another person to sign as a record of the relevant consent.

Withdrawal of consent to storage of embryos

- 2.33 Storage of an embryo requires the effective consent (in writing) of both of the persons whose gametes were used in the creation of that embryo. This consent may be withdrawn at any point up to the time that the embryo is used in treatment. If the consent of either of those persons is withdrawn, the embryo can no longer be kept in storage. The Government has considered whether this legal position remains appropriate, given concerns arising from cases where a relationship has broken down and the subsequent disagreement between the partners about use of the embryo.
- 2.34 The Government is not persuaded of the need for radical changes to this section of the law, or changes that would clearly favour the rights of one party over the other. However, **the Government proposes that there should be introduced a 'cooling off' period of up to one year following the withdrawal of consent to embryo storage by one of the persons whose gametes were used in the creation of that embryo.** This is to allow time for agreement to be reached between the parties on what should happen to the stored embryos. The embryos cannot be used by either party during the cooling off period, unless both parties consent.

3 Review of the common law provisions relating to the removal of gametes and of the consent provisions in the Human Fertilisation and Embryology Act 1990, published July 1998.

Statutory storage periods for gametes and embryos

- 2.35** The HFE Act sets out the maximum period of time for which gametes and embryos may be stored. The rationale for limits on storage periods is based on a combination of concerns around the uncertain effects of long-term storage, and ethical and legal problems which may arise over time.
- 2.36** The storage periods, set out in the Act, are ten years for gametes and five years for embryos, although there is a power to alter both of these periods by regulations drawn up by the Secretary of State and approved by Parliament. Regulations have been made under this section of the Act (in 1991 and 1996) which extended the standard storage periods for gametes and embryos respectively. The regulations allow longer storage of gametes or embryos in cases where the person has a medical condition which has rendered, or is likely to render them infertile and the stored gametes or embryos are intended for that person's own use in receiving treatment services.
- 2.37** The Government remains convinced of the need for some limits on the periods for which gametes and embryos may be stored, and believes that having clarity in the law (which may be adjusted from time to time by regulations) remains appropriate. However, the Government also accepts that there is a case, given greater experience of embryo storage available to date, for extending the baseline storage period for embryos. Therefore **the Government proposes to extend the statutory storage period for embryos from five years to ten years, bringing embryos into line with storage periods for gametes.**

Reproductive choices – screening and selection

- 2.38** Developments in reproductive technology have led to an increasing ability to screen and select embryos and, to a lesser extent, gametes as part of assisted reproduction. These developments have, to date, largely focussed on analyses to detect heritable genetic disorders and chromosomal abnormalities that would lead to serious disease or disability, or increased risk of miscarriage, and subsequently to select embryos free of the disorder for transfer to the patient. These interventions generally involve testing one or two cells removed from the embryo for analysis, and include preimplantation genetic diagnosis (PGD) and screening (PGS).
- 2.39** Less technical forms of selection of gametes and embryos have, however, been undertaken for many years. For example, as part of the process of donor insemination, the physical characteristics of the gamete donor are selected as far as possible in order that any resulting child may bear some resemblance to the persons receiving treatment. In addition, selection of those embryos which appear to have the greatest chance of successful implantation when transferred to the patient, is routine.

- 2.40 The range of disorders for which screening can (technically) be undertaken appears to be increasing at a rapid pace, and is not limited to the relatively straightforward case of a genetic disorder that would certainly and fatally affect a resulting child. Rather, as screening techniques are advanced together with an increasing knowledge of the influence of genetic factors, the ability to screen out disorders of lower penetrance, later onset or resulting from multiple factors, increases.

Screening and selection of embryos

- 2.41 The law, as it stands, does not refer explicitly to screening and selection of gametes and embryos. However, testing of *embryos* falls within the HFEA's remit, given its licensing powers in relation to embryos outside the body, and it has licensed this activity for several purposes including to prevent a range of serious medical conditions. This power has been the subject of legal challenge and has been confirmed by the House of Lords. Where the use of *gametes* falls within the HFEA's remit, it has, as a matter of policy, forbidden sex-selection for non-medical reasons.
- 2.42 The Government accepts that fears about the possible creation of 'designer babies' – meaning the selection of characteristics such as intelligence or musical ability – may be misplaced, or are at least likely to remain science fiction for some considerable time. Nevertheless, strong ethical concerns remain associated with screening and selection, including concerns about the destruction of embryos, and about the legitimacy of the choices which may be presented. Balanced against these concerns are the benefits arising from the prevention of serious diseases and disorders. Responses to the Department of Health's consultation revealed a wide range of opinions including from those who thought that screening should be allowed without any limits, and some who thought that no screening should be allowed at all. Overall, the Government believes that there is a general desire for the law to be clearer on this matter, and hence for Parliament to define some limits or criteria that apply to testing of embryos.
- 2.43 The Government will propose that the law is changed to include explicit criteria for the testing of embryos. In broad terms, legitimate purposes will be:
- to allow screening-out of genetic or chromosomal abnormalities which may lead to serious medical conditions or disabilities, or miscarriage
 - to enable the identification of a tissue match for a sibling suffering from a life-threatening illness, where umbilical cord blood is to be used in treatment of the sibling.

Deliberately screening-in a disease or disorder will be prohibited.

- 2.44 Considerable debate has surrounded the role of the regulator in relation to decisions to screen for particular medical conditions in individual cases, and the proper scope of decision-making apportioned to clinicians and patients within the law. The Government recognises the need to ensure that rules and regulations on the use of screening and selection balance potential benefits and harms to society and the direct effects on patients and their families. The Government sees an ongoing role for the regulator in ensuring consistency in practice, and the licensing of screening in accordance with criteria relating to the seriousness of the disorder in question. Further, the Government proposes that licensing of screening to identify a tissue match for a sibling with a life-threatening disease will, as now, be undertaken on a case by case basis.

Sex selection for non-medical reasons

- 2.45 Sex selection of embryos is currently undertaken for medical reasons because the probable manifestation of some conditions can be inferred according to the sex of the embryo. The same technology could also be used to select the sex of an embryo to be transferred to a woman for non-medical reasons. There is no mention of sex selection in the law at present, although the HFEA has made clear that it will not allow sex selection for social reasons. The HFEA undertook an extensive public consultation on this issue, as well as commissioning a MORI poll, and found strong opposition to non-medical sex selection.
- 2.46 The HFE Act does not currently apply to the use of 'fresh' gametes (i.e. non-donor gametes that are not stored), and new technology is presenting the possibility of effective techniques for mechanically sorting sperm into 'male' and 'female' chromosome-bearing samples. This activity will shortly be brought within the scope of regulation via implementation of the EU Tissue Directive insofar as quality and safety matters are concerned.
- 2.47 The Government has carefully considered a range of evidence and views in relation to sex selection for social reasons, including the view of the House of Commons Science and Technology Committee – which concluded that there was insufficient evidence to justify a ban on 'family balancing', where a family already has a number of children of one gender. However, **the Government is persuaded that sex selection for non-medical reasons within treatment services should be prohibited, including for 'family balancing'**. This reflects, in part, the strength of public opinion on this matter that this should not be a matter of choice open to potential parents. It also takes account of the possible effects – including internationally – on cultures where there is a clear preference for male children. The ban will apply both to embryos and to gametes, and the Government will consider the need for the ban to anticipate the possible advent of 'DIY' sperm sorting kits available to the public.

Genetic modification of gametes and embryos

- 2.48 The interventions described above involve selecting embryos according to their genetic make-up as determined by the natural processes involved in gamete formation and fertilisation. They do not involve any alteration of the genetic make-up of the gametes or embryos.
- 2.49 The Government has carefully considered arguments relating to interventions which would involve altering the genetic make-up of gametes or embryos. These include the prospect of being able to 'repair' damaged or faulty genes in order to prevent serious diseases or disorders. In theory, this would also mean that fewer embryos would need to be created than where screening and selection alone are used. However, the Government is persuaded that for the foreseeable future, and until such time as safety and efficacy are assured, genetic alterations of gametes and embryos should not be permitted for reproductive purposes. This position is consistent with a range of international agreements and conventions.
- 2.50 At present the HFE Act imposes a ban on "altering the genetic structure of any cell while it forms part of an embryo". Licences for treatment or for research cannot authorise this activity, although there is scope within the Act for regulations to be made setting out circumstances in which altering the genetic structure may be permitted under a research licence. No such regulations have been made to date. In practice, the HFEA has found that the scientific meaning of the phrase "altering the genetic structure" has proven difficult to interpret, and the Government intends to clarify its meaning in revised legislation for the avoidance of doubt, and to extend it to include gametes.
- 2.51 **The Government proposes that revised legislation will clearly ban genetic modification of the nuclear DNA of embryos and gametes for reproductive purposes.** This will reinforce the ban on using modified embryos in treatment, and apply the same principle to gametes. Alteration of this position would require future primary legislation. In addition, the Human Reproductive Cloning Act 2001 has the effect of precluding placing in a woman an embryo created otherwise than by fertilisation, providing an additional safeguard.
- 2.52 The Government is not, however, convinced of the need to preclude *research* activities that would involve altering the genetic structure of the embryo, as part of legitimate research projects. This position is, in principle, already recognised in the legislation by the provision of a secondary legislative power. **For research purposes only, the Government intends to remove the restriction on altering the genetic structure of a cell while it forms part of an embryo.** Licensed research projects intending to undertake this activity would still be required to meet all the stringent controls

applicable to embryo research projects including demonstrating that the use of embryos was necessary.

Information collection and confidentiality

- 2.53** The HFE Act makes the recording of certain information about the provision of licensed treatments mandatory, and requires clinics to provide data returns to the HFEA. This includes information about the treatment provided and the use of any donated gametes. The HFEA's central data register records this information, including data relating to treatment that did not result in a pregnancy. The register contains information about licensed treatments provided since August 1991, when the Act came into force.
- 2.54** The Act also places strict legal restrictions on the disclosure of information held by clinics and on the HFEA's data register. These restrictions were intended to safeguard the confidentiality of information relating to patients, donors and children. In fact, the original disclosure requirements in the Act were found, almost immediately, to be overly restrictive and were revised in 1992 to ensure that necessary activities, such as clinical audit, could be undertaken without undue impediment.
- 2.55** Despite the early amendment of the confidentiality restrictions of the Act, the Government became aware of widespread concerns that those restrictions remain too onerous and may impede activities such as follow-up research into the effectiveness of fertility treatments. A recent report⁴, published by the Medical Research Council recommended that a monitoring framework for assisted reproduction technologies should be established, based on core data collected by the HFEA and linked to other health records and health outcome data. The House of Commons Science and Technology Committee similarly recommended that the HFEA's existing data should be applied as far as possible to research studies, concluding that the current confidentiality restrictions were "unnecessarily onerous and inconsistent with the widespread use of assisted reproduction technologies".
- 2.56** The HFEA has developed a process of electronic data interchange with licensed centres via a secure internet connection to enable the rapid transmission of information and reduce the possibility of error. This development is reducing the administrative burden on clinics. However, the Government accepts that the maintenance of a comprehensive central database can only be fully justified if the data can be put to good and effective use. Therefore, **the Government proposes to revise the confidentiality restrictions in the HFE Act relating to the use of data on assisted reproduction treatments, so that it is more accessible for activities such as research.**

4 *Assisted reproduction: a safe, sound future*. Medical Research Council, 2004.

Information relating to gamete donors and donation

- 2.57 Under the HFE Act, the use of donated gametes in treatment services is subject to licensing. One of the key aspects of the regulatory scheme is the collection and maintenance of information relating to donors and to offspring resulting from the use of their donated gametes. This is a primary function of the data register kept by the HFEA. Under the terms of the Act, donor-conceived people can find out whether they are related to a person they intend to marry and, if aged 18 or over, can have access to information held on the register about the donor. Where information was provided to a licensed clinic after 31 March 2005, the donor-conceived person will, on reaching 18, have the right of access to identifying information including the name of the donor. The donor conceived person's parents will continue to be able to obtain non-identifying information about the donor from the treating clinic, or from the HFEA (RATE).
- 2.58 The Government does not propose to make major changes to the collection or maintenance of information about donors, nor does it propose to introduce any legal measure to force parents to tell their children if they were conceived through gamete donation, believing this to be a matter best encouraged through good practice rather than compulsion. However, the Government does propose to recognise in law some reciprocal rights of donors, and to widen access in relation to consanguinity. For the first time, **the law will make clear the right of donors to access limited non-identifying information about children conceived as a result of their donation. Also, the law will, in some circumstances, allow donors to be informed when their identifying details have been requested by those children. In addition, donor-conceived children will be able to find out if they have donor-conceived siblings, as part of the information accessible to them at age 18.**
- 2.59 An important function of the HFEA's register is to enable persons who intend to marry to find out whether they are related as a result of gamete donation. The Government proposes that access to information of this nature should be widened in order that **persons intending to form civil partnerships will be able to find out whether they are related as a result of gamete donation.** The law currently allows access to this information only in the context of marriage, and extension to include civil partnerships follows the principle of enshrining in law similar treatment of marriage and civil partnership. The Government will, however, also ensure that the possibility of providing access to this type of information for cohabiting couples is debated during the passage of legislation.

Surrogacy

- 2.60** Surrogacy refers to the situation where a woman makes a prior arrangement to carry a child with the intention that it will be handed over to someone else at birth. Surrogacy arrangements are not illegal in the UK, but there are a range of legal restrictions contained in the Surrogacy Arrangements Act 1985 which was enacted in response to widespread public concerns about commercial surrogacy. The 1985 Act prohibits the operation of commercial surrogacy agencies, and any advertising for a surrogate or of willingness to become a surrogate. It also makes clear that surrogacy arrangements are not legally enforceable contracts.
- 2.61** The HFE Act contains a provision enabling parties to a surrogacy arrangement to obtain a parental order in certain circumstances. The parental order, if granted by a court, has the effect of removing parenthood from the surrogate mother and reassigning it to the intending parents (generally described as the 'commissioning couple'). One of the conditions of the order is that only "reasonable expenses" have been paid to the surrogate. Around 50 parental orders are made each year.
- 2.62** Although surrogacy is not primarily a matter for the HFE Act, the Government has considered surrogacy arrangements as part of its review. The House of Commons Science and Technology Committee also recommended that an assessment of surrogacy arrangements should be made, including whether there was a need for separate amending legislation.
- 2.63** Whereas a majority of the Warnock Committee recommended extensive restrictions on the practice of surrogacy in its 1984 report, a minority thought that the door should not be closed entirely on surrogacy arrangements, and recommended that not-for-profit organisations should be allowed to operate in this area. This difference of opinion was based in part on whether surrogacy was expected to grow or to wither away. Over time, professional opinion has shifted to a position where surrogacy is recognised as an appropriate response to infertility in some circumstances – and this position is currently embodied in the HFEA's Code of Practice for licensed clinics.
- 2.64** Surrogacy, when all those involved are willing and well informed, can be an option for couples who cannot have children by any other means. The Government does not wish to restrict it unduly as a procedure for the alleviation of infertility, on a non-commercial basis. Therefore, **the Government intends, through revision to legislation, to clarify the extent to which not-for-profit organisations may undertake activities for the facilitation of surrogacy arrangements, including advertising their services.**

Status and legal parenthood

2.65 The HFE Act contains provisions about the parenthood of children born following assisted conception. These set out who has the legal status of “mother” and “father” following assisted conception using donated gametes, and a procedure for the reassignment of legal parenthood via parental orders in surrogacy cases. These provisions therefore affect matters ranging from an individual’s sense of self, to practical matters such as rights of inheritance.

2.66 As it stands, the Act provides that:

- the woman who gives birth to a child is treated in law as the legal mother
- where donor sperm (or an embryo created from it) is used and the woman is married, the husband is recognised in law as the legal father unless it is shown that he did not consent to his wife’s treatment
- where donor sperm (or an embryo created from it) is used and the woman is unmarried, but a man was being treated together with her at a licensed centre, then that man is recognised in law as the father
- in cases of surrogacy, a court may make a parental order in favour of a commissioning couple who meet certain conditions. These include the fact that the gametes of at least one of them have been used to create the child in question, and that the couple are married.

2.67 In undertaking its review of the HFE Act, the Government aimed to consider the extent to which changes may be needed to better recognise the wider range of people who seek and receive assisted reproduction treatment in the early 21st Century. The Government has also considered the impact of other legal changes that have occurred since the HFE Act came into force in 1991. For example, the coming into force of the Civil Partnership Act 2004 created a new legal relationship which two people of the same sex can form by registering as civil partners of each other. Important rights and responsibilities flow from forming a civil partnership including for civil partners to be assessed in the same way as spouses for child support.

2.68 Also, whereas it has for many years been possible for a single person to adopt a child, recent changes have enabled unmarried and same-sex couples jointly to adopt children. Other relevant changes include the fact that an unmarried man can acquire parental responsibility for a child through jointly registering the birth together with the child’s mother.

- 2.69 Given other legal changes since the HFE Act was enacted, and in particular, existing policy to create parity between civil partners and married couples, **the Government proposes to revise the status and legal parenthood provisions of the HFE Act to enable a greater range of persons to be recognised as parents following assisted reproduction.** This will involve introducing parenthood provisions for civil partners and other same-sex couples in line with those for married and unmarried couples respectively. Changes will apply both to the recognition of parental status following the use of donor gametes, and the acquisition of parental orders following surrogacy. In the latter case, this means that as well as married couples, civil partners and other couples in a stable relationship will be able to apply for a parental order.

Research involving embryos

- 2.70 The creation and use of embryos in research is permitted under the HFE Act subject to legally-defined limits, and licensing (on an individual project basis) by the HFEA. This position reflects considerable public and parliamentary debate, including a free vote on the principle of embryo research in 1990, and extension to the purposes for which research licences may be granted, in 2001.
- 2.71 The permissibility of research involving human embryos reflects the fact that advances in assisted reproduction – such as the development of *in vitro* fertilisation itself – could not have taken place without such research. Similarly, the law clearly permits research to be undertaken into matters such as increasing knowledge about congenital diseases, miscarriages, or heritable genetic conditions. Increasingly, stem cell research, including embryonic stem cell research, shows great promise for advances in the treatment of serious disease. The regulatory scheme set up by the HFE Act aims to ensure that the very real benefits to individuals and society arising from research can be gained whilst at the same time allaying concerns that human embryos may be created, used and destroyed frivolously or unnecessarily.
- 2.72 In announcing its review of the HFE Act, the Government made clear that it did not intend to open up the fundamental principles of the legislation, which include the permissibility of the creation and use of embryos for research within limits and subject to regulatory oversight. The Government therefore does not propose to alter this position, including parameters such as the maximum time limit on the development of embryos *in vitro*, which will remain at 14 days. However, the Government does propose to make some revisions to the Act in relation to embryo research to ensure that legitimate research can continue to flourish, and that controls remain up to date.

Research purposes

2.73 The HFEA may only license projects involving embryos if it appears that the activity is necessary or desirable for one or more of the research purposes listed in the Act, and that the use of embryos is necessary. The current list of research purposes is:

- promoting advances in the treatment of infertility
- increasing knowledge about the causes of congenital disease
- increasing knowledge about the causes of miscarriages
- developing more effective techniques of contraception
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation
- increasing knowledge about the development of embryos
- increasing knowledge about serious disease, or enabling any such knowledge to be applied in developing treatments for serious disease.

2.74 The Government believes that the presence of a list of legitimate research purposes provides a valuable, and public, statement of the reasons for which embryo research may be undertaken, and does not propose to make radical changes to the current list. However, the Government is aware of concerns that whilst the list clearly allows *applied* research into serious disease, more basic research (which may be necessary to underpin the applied research) is not mentioned explicitly and that this could give rise to doubt about its permissibility. Similarly, whereas the law refers to serious *disease*, it does not refer explicitly also to *injury* or other damage (for example, spinal cord injuries). Therefore, **the Government proposes to make clear in legislation that basic (as well as applied) embryo research is permissible subject to the controls of the HFE Act. Also, the Government proposes to make clear that research into serious injuries (such as spinal cord injuries) is permissible, as well as research into serious diseases as at present.**

Activities authorised by research licences

2.75 In addition to requiring conformity to legally specified research purposes, the HFE Act lists a number of activities that cannot be authorised by a research licence, or which are simply prohibited. These include:

- placing in a woman a live embryo other than a human embryo, or live gametes other than human gametes
- placing a human embryo in an animal

- replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo.

In addition, Parliament can set out in regulations any further circumstances in which keeping or using an embryo is not to be allowed.

- 2.76 The Government does not propose to make any alteration to the position that only human embryos or gametes may be placed in a woman, for any purpose. Also, the Government is not convinced that there is any compelling argument to allow a human embryo to be placed in an animal for any purpose, and does not propose to alter this position.
- 2.77 However, the Government has carefully considered whether the restriction on replacing the nucleus of a cell of an embryo with another nucleus remains justified. The aim of this restriction was originally to prevent the possibility of *reproductive* cloning, a role now performed by the Human Reproductive Cloning Act 2001. The creation of embryos by the process of *therapeutic* cloning is, however, permitted under research licences for, for example, research into serious diseases. There is therefore an inconsistency in the law that may impede useful avenues of research, and which is unnecessary for the prevention of reproductive cloning. **The Government proposes to remove the restriction on replacing the nucleus of a cell of an embryo for research purposes only, subject to the controls of the HFE Act.**

Training of embryologists

- 2.78 The law as it stands lists a range of activities that may be permitted under the authority of a licence issued by the HFEA. There is, however, no reference in the Act to the training of persons who carry out those activities. It is clear that, in allowing activities to take place, it is also necessary that persons are able to be trained to an appropriate level, and the Government intends to remove any confusion on this point. Therefore, **the Government proposes that the use of embryos for training in treatment and research techniques will clearly be permissible under the authority of a licence.**

Creation of embryos for therapeutic use

- 2.79 Research using embryos is permissible for the purpose of developing treatments for serious diseases, under a research licence granted by the HFEA. A number of avenues of research are being pursued and any may lead to breakthroughs in the treatment of serious diseases. However, it is possible that this type of research may ultimately lead to proven therapies which continue to require the creation of embryos for the direct therapeutic benefit of the patient. At such time as this therapy was proven to be safe

and effective, it would be difficult to continue to consider it as *research*, bringing into question whether it could continue to be licensed as research by the regulator. There is not, at present, scope for the regulator to license this activity under any other type of licence.

- 2.80 Whereas the Government does not propose any immediate changes to the legislation to address this situation, the Government will nevertheless ensure that this issue is debated in Parliament as part of the consideration of revised legislation, and the need for the law to anticipate the scenario in question.

Embryos combining human and non-human material

- 2.81 At present, the HFE Act allows the mixing of human and animal gametes (under licence) only for the purpose of testing the fertility or normality of sperm, provided that the result of the mixed gametes is destroyed when the test is complete (and definitely no later than the two cell stage). This restriction reflected public concerns about the possibilities of creating “hybrid” embryos (for example, by the fertilisation of a human egg with the sperm of another species), or “chimeras” (for example, by fusing the cells of a human embryo with cells from the embryo of another species).
- 2.82 The law does not, however, refer to more novel processes of embryo creation that have been developed since the Act was passed, and which, in theory, could be used to create embryos combining human and animal material. The extent to which the law and regulation would apply to embryos created in these circumstances is not sufficiently clear, although the law would clearly prevent such embryos being placed in a woman. In some circumstances the embryo created could be, genetically speaking, almost entirely human and therefore could fall within the regulatory controls applicable to human embryos.
- 2.83 The Government recognises that there is considerable public unease with the possible creation of embryos combining human and animal material, and particularly to the prospect that such entities could be brought to term. This view was strongly represented in responses to the Department of Health’s consultation. However, the Government is also aware of the potential benefits to, for example, research into serious diseases that could accrue from laboratory research in this area. Other human-animal cell fusion products have been widely used in biosciences research for many years, including in the development of treatments for some types of breast cancer. Reasons for wanting to create hybrid or chimera embryos include:
- testing the capacity of embryonic stem cells to differentiate into other cell types
 - to derive embryonic stem cells for research, circumventing the need to use scarce human eggs (which would otherwise be used in fertility treatment).

- 2.84 The House of Commons Science and Technology Committee has also recommended that revised legislation should permit the creation of hybrid and chimera embryos for research provided they are destroyed in line with the 14 day rule applicable to human embryos.
- 2.85 The Government intends to put this matter to Parliament for further consideration. **Revised legislation will clarify the extent to which the law and regulation applies to embryos combining human and animal material. The Government will propose that the creation of hybrid and chimera embryos *in vitro*, should not be allowed. However, the Government also proposes that the law will contain a power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos *in vitro* may in future be allowed under licence, for research purposes only.**

3. The Regulatory Authority for Tissue and Embryos (RATE)

Introduction

- 3.1 The Department of Health launched its review of its arm's length bodies (ALBs) as a contribution to the wider Government aim of minimising and modernising the bureaucratic overhead that goes with the provision of public services. The *Report on Reconfiguring the Department of Health's Arm's Length Bodies* (July 2004) set out the rationale behind the ALB Review's recommendations for change and the proposed grouping of ALBs, including the replacement of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) with a single body.
- 3.2 The establishment of RATE provides an opportunity for the creation of a single regulatory body responsible for the regulation and inspection of all functions relating to the whole range of human tissue – cells, tissues, organs, gametes and embryos. It will also take over from the Medicines and Healthcare Products Regulatory Agency (MHRA) the responsibility for the regulation of the procurement, testing, storage and distribution of blood and blood products. As such, RATE will be able to ensure that in these closely linked areas, common principles and standards are applied wherever that is appropriate. It will ensure that the risk of overlap between these sectors is minimised; and that there is continuity at the interface between related areas, for example between embryo research and cell therapies.
- 3.3 The Government recognises that the HFEA has established a significant national and international reputation, and that the HTA has started to establish itself within the field and has received much praise for its approach. Against this background, the Government is fully aware of the need to ensure that RATE maintains the necessary continuity to give those regulated the confidence in its ability to operate across a broad sector of regulation. As such, the process will be carefully managed so as to ensure a smooth transition.
- 3.4 While RATE will bring a consistency of approach where needed, the requirement for proportionate, targeted regulation also means that it should maintain distinct approaches where that is appropriate. RATE, as with HFEA and HTA, will maintain expertise in each field through its regulatory activities as well as through the expert advisory structure that the Government is proposing. The introduction of Expert Advisory Panels in each key area, as described below, will secure a transparent

approach and broad expert input to help minimise the risk that a relatively small number of people might be involved in considering major issues.

Remit of RATE

- 3.5 The general remit of RATE will reflect the current remits of the HFEA and the HTA, and of the MHRA insofar as it relates to the regulation of the procurement, testing and distribution of blood and blood products. RATE will therefore acquire the role of 'competent authority' in respect of the EU Directives on Blood and Blood Components, and on Tissues and Cells. As such it will be responsible for licensing and inspection functions and for setting standards through Codes of Practice.
- 3.6 Currently the HFEA and the HTA general functions also include the provision of information and advice to the public and to people carrying out activities within their remit; monitoring developments in their respective fields; and providing advice to Ministers as required. The Government proposes that these functions should continue, and it will bring them together under RATE.
- 3.7 The role of RATE will therefore be:
- to provide general oversight of the area of the donation, procurement, storage, use and disposal of human blood, organs, tissue and cells including tissue and cells donated for reproductive use
 - to licence, inspect and regulate specific activities including the creation and use of embryos *in vitro* for treatment and research; human tissue banking, *post mortem* practice, anatomical examination and public display
 - to advise Ministers on developments in society, science or medicine that might significantly affect the practice of regulated activities
 - to provide to the public and to persons carrying on activities within its remit, such information and advice as it considers appropriate about the nature and purpose of such activities.

Main functions

- 3.8 RATE will be an independent statutory body with regulatory powers and responsibilities that broadly reflect those currently held by the HFEA and the HTA, and the MHRA in respect of blood. In order to carry out its general role, RATE will have a range of specific functions that will include:
- inspection and licensing powers for specified activities

- publication of statutory codes of practice setting out the standards expected of licensed and registered centres or persons
- maintaining other guidance for practitioners, and information for members of the public
- data collection reporting systems
- maintenance of a register of infertility treatment, including donors
- the publication of an annual report, to be laid before Parliament
- regulation of live donor transplants.

Licensable activities

- 3.9 The activities that will be subject to licensing will reflect those that are currently licensed by the HFEA and the HTA and authorised by the MHRA. The introduction of RATE will not in itself involve extending the range of licensable activities.

The functioning of RATE

- 3.10 In establishing RATE, the opportunity arises to develop a model that draws on the best of the HFEA and the HTA. Careful consideration has been given, however, to how it will maintain access to sufficient expertise covering the wider areas for which it has responsibility and to the necessary mechanisms to take account of the full breadth of public and professional opinion and to engage with the public more widely.
- 3.11 The Government proposes that RATE should consist of individuals appointed by the Secretary of State together with the Devolved Administrations. The Government recognises that a single Board will necessarily be limited in size, and will be unable to include direct representation of all the interests of those engaged in or affected by the areas of activity within its remit. Already the relatively large membership of the HFEA and the HTA provide only limited representation within their respective areas, and it would be impossible to manage a RATE membership of a size that could achieve a full spectrum of direct representation. The Government believes, therefore, that there is significant advantage in establishing a smaller board that incorporates the skills and expertise that are needed for taking a more strategic role, whilst securing a broader range of expert input through a formal and transparent advisory structure.
- 3.12 The Government's proposal is that while the legislation will not specify the number of members to be appointed to RATE, the number should be smaller than the current HFEA or HTA boards (which are 21 and 17 respectively). The Chair and members will be appointed by the NHS Appointments Commission on behalf of the Secretary of State, as is currently the case for the HFEA and the HTA. These appointments will

be made in accordance with the guidance issued by the Commissioner for Public Appointments, based on the 'Nolan' principles requiring transparent processes and free and open competition. The Chair and the majority of the membership will be lay, in that they will not have or have not had a professional interest in any kinds of activity within the remit of the Authority.

- 3.13 The Board will be supported by Expert Advisory Panels (EAPs) to ensure that expertise is directly and consistently available in all areas of activity within its remit. RATE will be required to establish EAPs covering assisted reproduction and embryology; transplantation and transfusion; and anatomy and pathology, but will be able to establish other EAPs giving advice and support in other areas as necessary.

- 3.14 It will be for RATE to decide the expertise it needs on the EAPs. However, the Government will expect them to include technical specialists as well as people from other disciplines such as ethics, law, patient interests and others, in order to provide a broad range of experience and advice. In this way the board will have access to a wide cross section of high quality support, advice and opinion and significant contact with leaders in each field.

- 3.15 Although the EAPs will have no executive powers, and the RATE Board will be free to consider how to use their advice, the panels will be chaired by members of the RATE Board, so that they will be able to represent the views of the Panels directly. The EAPs will not replace the need for RATE to consult widely, as HFEA and HTA do at present.

- 3.16 RATE will maintain an executive staff, headed by a Chief Executive appointed by the board, that will carry out the day to day functions of the authority, operating within a policy framework established by the membership. It will be for the RATE members to set down the procedures, informed by advice from the EAPs, by which the executive operates and to delegate functions and activities as appropriate.

Licensing role

- 3.17 At present HFEA members make licensing decisions as they are required to make up licence committees. By contrast, HTA licensing decisions are not required to be made by HTA members. The Government believes that RATE will operate most effectively with a flexible system whereby it is able to establish its own licensing procedures within the framework set out in the Act. This will include systems for the review of decisions and appeals, which the Government proposes will be heard by RATE Members.

Approval of live transplants

- 3.18 The approval of the donation by living donors of organs and (in the case of children or adults unable to give consent) bone marrow was a responsibility acquired by the HTA on 1 September 2006. Under this system the HTA gives approval on a case-by-case basis in accordance with a set of published criteria. The Human Tissue Act and associated Regulations allow the HTA to delegate most decisions to its executive staff, but certain cases – principally those involving bone marrow donation by children who are not capable of themselves giving consent – must be considered by a panel of authority members. The Government proposes that approach should continue under RATE.

Codes and guidance

- 3.19 Both the HFEA and the HTA currently have a statutory obligation to prepare and publish Codes of Practice. The Government believes that the duty to maintain Codes of Practice should continue under RATE, covering the same areas that are currently dealt with under the existing legislation. The procedures for publishing the Codes will be streamlined. They will continue to be subject to Ministerial approval in consultation with the Devolved Administrations, and will have to be laid before Parliament.

Summary

- 3.20 The Government believes that these highly specialised areas, with particularly sensitive ethical and social concerns, still need to have specific legislative controls not only to reassure Parliament and the public, but also to provide a secure and supportive environment in which professionals can work.
- 3.21 It is important that Parliament sets the boundaries and establishes what is and is not permissible within a clear framework. This approach gives the public confidence in the regulation of this sensitive and complex area and ensures close monitoring, whilst allowing necessary flexibility to take account of developments in medicine and technology. The HFEA model, on which the HTA was based, and on which RATE will ultimately be based, has been a successful one. It has operated to international acclaim for 15 years, but will benefit from updating where this is necessary. The establishment of RATE gives us the opportunity to ensure we draw on the best of both organisations.

4. Summary table of proposals

	Proposal	Current position	Paragraph
1	The current model of regulation, whereby Parliament sets the prohibitions and parameters within which a statutory authority licenses activities should continue.	The Human Fertilisation & Embryology (HFE) Act sets out parameters within which the Human Fertilisation & Embryology Authority (HFEA) licenses activities.	2.4
2	Activities involving the creation, keeping and use of embryos outside the body, or the use of donated gametes, should continue to be subject to licensing by an independent regulator.	The law requires that these activities may only be undertaken under the authority of a licence from the HFEA.	2.9
3	All human embryos outside the body, regardless of the manner of their creation, will be within the scope of regulation.	The current wording of the Act in relation to embryos has cast doubt on the application of the law to embryos created by novel processes.	2.11
4	The law will continue to treat 'eggs in the process of fertilisation' in the same way as embryos, and this will also apply to eggs undergoing other processes of embryo creation.	The law currently includes 'eggs in the process of fertilisation' within the meaning of the term 'embryo', for the avoidance of doubt. It does not mention other processes of embryo creation.	2.12
5	Artificial gametes. The Government proposes a ban on the use of non-naturally occurring gametes (cells not originating in the testes or ovaries) in assisted reproduction treatment.	The law does not currently refer to artificial gametes.	2.15
6	The Government proposes to retain a duty for treatment centres to consider the welfare of the child who may be born as a result of treatment (or any other child who may be affected).	The law requires that account is taken of the welfare of the child (including the need for a father) before providing treatment. The HFEA is obliged to provide practical guidance on this duty.	2.23
7	On balance, the Government has decided to propose that the reference to the need for a father (in consideration of the welfare of the child) should be removed from the Act.	See above.	2.26

Proposal	Current position	Paragraph
8 The law will enable the storage of gametes from persons lacking capacity where the gametes have been lawfully removed in the best interests of that person, without written consent, where medical opinion indicates that the person is likely to gain/ regain capacity.	There is currently no provision to make exceptions to the rule requiring written consent for storage, even where this would be in the patient's best interests.	2.31
9 There should be a 'cooling off' period of up to one year following the withdrawal of consent to embryo storage by one of the persons whose gametes were used in the creation of the embryo.	Withdrawal of consent from either party removes authority for continued storage.	2.34
10 The Government proposes to extend the statutory storage period for embryos from five years to ten years, bringing embryos into line with gametes.	The current statutory storage period for embryos is five years subject to exceptions as set out in regulations.	2.37
11 The law will include explicit criteria for the testing of embryos. Legitimate purposes will be (i) screening out genetic or chromosomal abnormalities leading to serious medical conditions, disabilities, or miscarriage (ii) tissue typing to provide umbilical cord blood to treat a sibling suffering a life threatening illness. Deliberately screening-in a disease or disorder will be prohibited. The regulator will license these activities to ensure consistency, and will consider tissue typing applications on a case by case basis.	The law does not refer explicitly to embryo testing. The HFEA is able to license this activity, although this has been subject to legal challenge.	2.43
12 Sex selection for non-medical reasons within treatment services will be prohibited, including for 'family balancing'.	The law does not mention sex selection. It is banned for non-medical reasons in relation to embryos as a matter of HFEA policy, and in relation to gametes insofar as these fall within the HFEA's remit.	2.47

Proposal	Current position	Paragraph
13 The Government proposes that the law will clearly ban genetic modification of the nuclear DNA of embryos and gametes for reproductive purposes.	Treatment licences cannot authorise "altering the genetic structure of a cell while it forms part of an embryo". Research licences have the same restriction, subject to a regulation-making power. The scientific meaning of "altering the genetic structure" has proven difficult to interpret in practice.	2.51
14 For research purposes only, the restriction on altering the genetic structure of a cell while it forms part of an embryo will be removed.	See above.	2.52
15 The Government proposes to revise the confidentiality restrictions in the HFE Act relating to the use of data on assisted reproduction treatments, so that it is more accessible for activities such as research.	The HFE Act contains very strict criteria on the disclosure of information from the HFEA's register of information about licensed treatment. Despite amendment in 1992, these are widely seen as impeding the effective use of the database for uses such as follow up research.	2.56
16 The law will make clear that gamete donors will be able to access limited, non-identifying information about children conceived as a result of their donation. Donors will be able to be informed when their identifying details have been requested by those children (from age 18).	The law does not currently contain any explicit recognition of a right of donors to be told when a child is born from their donation or to be informed when identifying information about the donor is divulged to them.	2.58
17 Donor-conceived children will be able to find out if they have donor-conceived siblings, as part of the information accessible to them from age 18.	The law does not contain any reference to access to information about siblings.	2.58
18 Persons intending to form civil partnerships will be able to find out whether they are related as a result of gamete donation.	The law currently enables persons wishing to marry to find out if they are related as a result of gamete donation.	2.59

Proposal	Current position	Paragraph
19 The extent to which not-for-profit organisations may undertake activities for the facilitation of surrogacy arrangements will be clarified.	The Surrogacy Arrangements Act 1985 imposes a range of restrictions on surrogacy, aimed at preventing commercial arrangements.	2.64
20 The status and legal parenthood provisions of the HFE Act will be revised to enable a greater range of persons to be recognised as parents following assisted reproduction.	The Act currently assigns parental status to married men, or men treated together with a woman, where donor sperm is used. It also provides a mechanism for reassigning parental status in surrogacy cases.	2.69
21 Legislation will make clear that basic (as well as applied) embryo research is permissible subject to the controls of the HFE Act. Also, the law will be clear that research into serious injuries (such as spinal cord injuries) is permissible, as well as research into serious diseases as at present.	The Act refers to research into serious disease, but does not explicitly mention research that may be a necessary precursor to such projects. Similarly it does not explicitly mention damage or injury.	2.74
22 The Government proposes to remove the restriction on replacing the nucleus of a cell of an embryo for research purposes only, subject to the controls of the HFE Act.	The Act bans replacement of the nucleus of a cell of an embryo with another nucleus. The purpose of this provision was to preclude reproductive cloning – a role now fulfilled by the Human Reproductive Cloning Act 2001.	2.77
23 The Government proposes that the use of embryos for training in treatment and research techniques will clearly be permissible under the authority of a licence.	The Act does not refer to training explicitly, leading to uncertainty about what activities may be undertaken by trainees.	2.78
24 The Government will propose that the creation of hybrid and chimera embryos <i>in vitro</i> , should not be allowed. However, the Government also proposes that the law will contain a power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos <i>in vitro</i> may in future be allowed under licence, for research purposes only.	The Act allows the mixing of human and animal gametes under licence for the purpose of testing the fertility of sperm (using a hamster egg). It does not refer to novel processes for the creation of embryos combining human and animal material.	2.85

Proposal	Current position	Paragraph
<p>25 RATE. The Government proposes to replace the HFEA and the HTA with a single regulator – the Regulatory Authority for Tissue and Embryos. RATE will be the single competent authority acting as the regulator under the EU Blood, and Tissues and Cells Directives.</p>	<p>The HFEA and HTA are separately established statutory bodies. The Medicines and Healthcare products Regulatory Agency currently carries out the relevant regulatory functions in relation to the EU Blood Directive.</p>	Section 3

Annex A: Partial Regulatory Impact Assessment

Title of proposal

- A1 Review of the Human Fertilisation and Embryology Act (and establishment of the Regulatory Authority for Tissue and Embryos).

Purpose and intended effect

Objectives

- A2 The measure is intended to (a) replace two bodies involved in the regulation of human tissue with a single authority and (b) to update legislation regulating assisted reproduction and embryo research.
- A3 Replacement of the two bodies will rationalise regulation and produce savings. Updating the law on assisted reproduction and embryo research will ensure that it remains effective and fit for purpose in the 21st century.

Background

- A4 Current legislation (principally the Human Fertilisation and Embryology Act 1990, and the Human Tissue Act 2004) imposes a range of regulatory measures to activities involving human organs, tissue and cells, including gametes (sperm and eggs) and embryos. The Human Fertilisation and Embryology Act was largely based on the conclusions of a Committee of Inquiry published in 1984, and subsequent extensive public consultation, which followed the birth of the first child conceived through *in vitro* fertilisation in 1978. The Human Tissue Act followed a broad and fundamental review of the law on human organs and tissues in 2002, preceded by public inquiries that established that organs and tissues from people who had died had often been removed, stored or used without proper consent.
- A5 The Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) are statutory licensing bodies. The remits of both organisations involve licensing and inspection, producing codes of practice for licence holders, and providing advice to Ministers as required. Both organisations will be “competent authorities” responsible for overseeing the requirements of European Union Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.⁵

5 Referred to hereafter as the European Tissue Directive

- A6** The Department of Health undertook a review of its arm's length bodies as part of a wider programme of measures to improve efficiency and cut bureaucracy. Replacement of the HFEA and HTA with a single authority (RATE) will help to meet the objective of the review to reduce the burden on the frontline and free up more resources for the delivery of services to patients. RATE will also take over the regulation required under the EU Blood Directives, of the sourcing, testing and supply of blood and blood products from the Medicines and Healthcare Products Regulatory Agency (MHRA). The Government's decision to establish RATE was announced in July 2004.

Rationale for Government intervention

- A7** The HFE Act was drawn up on the basis that certain activities involving human embryos outside the body, or the use of stored or donated gametes, demanded active regulation and definite legal limits. Ultimately, the Government believes that the force of law remains justified in the distribution of permissions, rights, responsibilities and prohibitions for the development and use of human reproductive technologies. Law and active regulation are necessary to set out and monitor a system of public oversight and accountability, taking account of the principles of good regulation.
- A8** The Government announced in January 2004 that it would undertake a review of the HFE Act, in particular to take account of factors such as the development of new technologies and procedures, international developments in standards, possible changes in public attitudes on complex ethical issues and the need to ensure the effectiveness of regulation. In undertaking its review, the Government has also taken account of the House of Commons Science and Technology Committee's extensive report and recommendations on human reproductive technologies and the law, published in March 2005.
- A9** The Government does not propose to make any changes to the substantive provisions of the Human Tissue Act 2004 – such as the requirement for appropriate consent to the removal of organs and other tissue from the body of a deceased person – other than any changes consequential upon the replacement of the Human Tissue Authority by the Regulatory Authority for Tissue and Embryos (RATE). The provisions of the Human Tissue Act were conclusively debated in the previous Parliament.

Consultation

- A10** The Department of Health published a consultation paper on 16 August 2005. The closing date for responses was 25 November 2005. A total of 535 responses were received from a wide range of stakeholders including licence holders, patient's representatives, professional bodies and individual members of the public. A report

summarising the landscape of arguments put forward in response to the consultation document was prepared by People Science and Policy Ltd and published on 30 March 2006. It is available from the Department of Health's website at www.dh.gov.uk/Consultations/ResponsesToConsultations/fs/en

Options

A11 Three options have been identified:

- Option 1 – Do nothing
- Option 2 – De-regulation
- Option 3 – Revision of current regulation and regulatory structures

Option 1: Do nothing

A12 This option means, essentially, retaining the current regulatory provisions and structures. This would risk the law becoming outmoded by, for example, new technological developments, or outdated in relation to the other factors mentioned above that led to the Government's decision to review the law in this area. It would also miss the opportunity to streamline regulation by replacing two non-departmental public bodies with one.

Option 2: De-regulation

A13 This option means, essentially, removing the current regulatory requirements in whole or in part – for example it could mean retaining certain prohibitions, but removing some licensing requirements. The requirements of the European Tissue Directive relating to quality and safety of blood and blood products, tissue and cells would still apply, however these do not extend to 'ethical' matters or to research *in vitro*. This would leave a range of activities involving, for example, the use of embryos outside the body or donated gametes without specific regulation beyond quality and safety aspects. Risks include the opening up of inconsistencies in the way in which specific and closely related cases are handled.

Option 3: Revision of current regulation and regulatory structures

A14 This option means reviewing current arrangements and structures and making changes where it is judged necessary taking account of a range of factors. It carries risks associated with change such as possible planning blight, uncertainty and transitional costs.

Costs and benefits

Sectors and groups affected

A15 Currently there are 85 HFEA-licensed treatment clinics, mainly providing privately-funded treatment, plus an additional 8 centres licensed to store gametes or embryos, and 33 licensed embryo research projects. Licensed centres, their patients, donors, and persons involved in licensable research, will be directly affected by the proposed measure. In addition, this regulatory impact assessment presupposes implementation of the requirements of the aforementioned European Tissue Directive from April 2007, which will expand the scope of licensable activities to include, for example, use of non-donor gametes within treatment services. Therefore centres licensed as a result of the Directive will also be directly affected by the proposed RATE Act (a separate RIA will accompany regulations implementing the Directive). In terms of indirect effect, regulation governing the use and development of assisted reproduction, and the use of human embryos in research aimed at the advance of assisted reproduction techniques or the discovery of treatments for serious disease, is clearly of wider interest to society as a whole.

A16 The legislation will be reserved as far as assisted reproduction and embryo research aspects are concerned (mirroring current extent of the Human Fertilisation and Embryology Act 1990), and will apply to England, Wales and Northern Ireland as far as human tissue is concerned (mirroring current extent of the Human Tissue Act 2004). The regulator will have powers to assist any other public authority in the UK, and will therefore be able to undertake functions in relation to human tissue in Scotland if commissioned to do so.

Benefits

Option 1: Do nothing

A17 In maintaining the status quo, this option has some merits in the short term including the temporary avoidance of costs associated with change.

Option 2: De-regulation

A18 This option has potential benefits in terms of the avoidance of the costs of regulation (see below), which are largely recovered from licence-holders and generally passed on to service users. Arguably, other benefits could accrue from fewer constraints on clinical and academic freedom from regulatory intervention.

Option 3: Revision of current regulation and regulatory structures

A19 This option (as envisaged under the proposed RATE Bill) has benefits arising from the rationalisation of regulatory structures, increased clarity (and reduced scope for legal challenge) in the substantive legal provisions, and keeping pace with current and

anticipated changes in technology and attitudes. Replacing two arm's length bodies with one will produce savings in operating costs and the fees that the new body will charge licence holders to cover the costs of regulation. The estimated saving is approximately £700,000 per annum.

Costs

Option 1: Do nothing

- A20** Costs (not including the current costs of regulation per se) associated with this option are difficult to quantify. They include both costs arising from, for example, legal challenges as technological advances overtake the wording of the Act, and 'opportunity costs' as a result of increasing legal uncertainty impacting on, for example, investment decisions. Further, this option would continue to incur the costs of running two separate regulatory authorities.

Option 2: De-regulation

- A21** *Prima facie*, this option would release the current direct costs of regulation (other than costs of, for example, licensing and inspection associated with the requirements of the European Tissue Directive which would address quality and safety aspects). The direct compliance costs of current regulation under the HFEA are as follows: licence fee income for 2004/05 was £4.125m. This breaks down into initial licence fees of £500 (£200 for storage only licences), then fees of £103 per cycle of *in vitro* fertilisation, and £51 per donor insemination cycle. A fee of £500 is charged to small research projects, and £750 to larger projects.
- A22** The costs of compliance with the HFEA's Code of Practice for licence holders, other than licence fees, have been estimated, as part of a cross-Whitehall project to calculate and reduce administrative burdens, to be in the region of £10 million. The extent to which these costs would not apply in the absence of the current scheme of regulation would depend on the costs arising due to other statutory requirements (in particular the European Tissue Directive) that would remain, and compliance with non-statutory regulation and other professional good practice.
- A23** It is impossible to quantify, however, any 'costs' arising from public perception of a lack of adequate regulation of activities in this area. This point was also made by the Better Regulation Task Force, in its 2003 report *Scientific Research: Innovation with Controls*, which noted that "the UK is seen as a world leader in embryonic stem cell research, and this is largely due to the effective regulations that control it".

Option 3: Revision of current regulation and regulatory structures

- A24** It is proposed that the new regulatory authority (RATE) would be funded in part by grant-in-aid from the Department, with the bulk of the costs of regulation recovered via licence fees, as at present.
- A25** There will, however, be costs incurred during transition to the new arrangements, included the cost of setting up RATE. It is expected, however, that these will be minimised in the interim through close joint working and sharing of 'back office' functions of the HFEA and the HTA. Current estimates of transitional costs are in the range £2m to £6m depending mainly upon issues of shared accommodation and ultimate location of RATE.

Benefits and costs of specific proposals

- A26** A full Regulatory Impact Assessment will accompany draft legislation when published.
- A27** For the vast bulk of the proposed changes to the HFE Act, the Government envisages their effect being cost-neutral or unquantifiable in monetary terms or in terms of direct effects. For example, it is intended that the definition of the term "embryo" be updated to reflect new techniques of embryo creation which have arisen since the passage of the original legislation. This will, in effect, secure the status quo in regulatory terms, and provide future-proofing against subsequent developments. The benefits accruing from avenues of scientific research using new forms of embryo creation within a more certain (rather than a less certain) regulatory environment are, however, difficult to establish quantitatively. Similarly, other proposed changes seek to put into statute requirements which already apply in practice via the powers granted to the regulator. For example, there is already a *de facto* ban on the use of embryo screening and selection other than for serious non-medical reasons through the HFEA's licensing criteria (listed in its code of practice for licence holders).
- A28** In some areas, however, there will be a clear gain for certain groups. Recognition of the advent of civil partnerships will bring benefits to those persons affected. For example, direct attribution of parental status will obviate the need to initiate adoption procedures and any associated costs. Extended storage limits can be expected to benefit persons choosing to store embryos and those who are responsible for their storage in terms of reduced paperwork. Less strict limits on access to information held on the HFEA's register of information about infertility treatments can be expected to be of general benefit, particularly by increasing opportunities for follow-up research and any subsequent improvements made to treatment regimes for the benefit of future patients.

Small Firms Impact Test/ Competition assessment

- A29** Many licensed clinics (which are predominantly private sector based) and research centres can be considered to be small firms. The Government believes that the proposed measure, by reducing direct costs of regulation, will have a positive effect on small firms and competition more generally. At the same time increased clarity in the law will also be of benefit in terms of investment decisions.

Rural Impact

- A30** The proposals would not have any adverse rural impact.

Race Impact

- A31** The proposals would not have any adverse race impact.

Enforcement, sanctions and monitoring

- A32** Existing law in this area is enforced through a range of sanctions including criminal penalties as well as measures attaching to licensing. The remits of both the HFEA and the HTA have inspection and monitoring functions. The Government proposes that a similar range of measures will continue with the advent of RATE, but this will be reviewed in light of the emerging issues following the Macrory review of penalties.⁶
- A33** The existing regulatory bodies have a specific function to monitor developments in their fields of interest and it is proposed that RATE will retain this function, including to advise the Secretary of State as required. The effectiveness of RATE will be monitored through the usual procedures for oversight of arms length bodies, including clearance and monitoring of business plans and annual accountability reviews.

Summary and conclusion

- A34** The Government believes that primary legislation, and regulation by a dedicated authority remain necessary in response to public concerns about the use of reproductive technologies and human tissue (and appropriate in order to meet international obligations under the European Tissue Directive). Present law on assisted reproduction and embryo research needs to be updated to take account of developments of new technologies, changes in public attitudes and to ensure that regulation remains effective and fit for purpose, and continue to secure public confidence. Replacement of two existing regulatory bodies with a single authority will rationalise regulation and produce savings.

⁶ *Regulatory Justice: Sanctioning in a post-Hampton World*, Cabinet Office, May 2006.

Annex B: List of related legislation⁷

Primary legislation

- The Surrogacy Arrangements Act 1985 (c. 49)
- Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54)
- The Human Reproductive Cloning Act 2001 (c. 23)
- The Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24)
- The Human Tissue Act 2004 (c. 30).

Secondary legislation

- The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 No. 1540
- The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991 No. 1588
- The Human Fertilisation and Embryology (Licence Committee and Appeals) Regulations 1991 No. 1889
- The Parental Orders (Human Fertilisation and Embryology) Regulations 1994 No. 2767
- The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 No. 375
- The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 No. 188
- Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 No. 1511.

⁷ These are available online at www.opsi.gov.uk or published copies can be purchased from TSO.

Annex C: Further reading, addresses and links

- C1 Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cm 9314, July 1984, ISBN 0105437905⁸.
- C2 Human Fertilisation and Embryology Act (c. 37). (Can be viewed online at www.opsi.gov.uk or purchased in hard copy from TSO).
- C3 House of Commons Science and Technology Committee Fifth Report of Session 2004-05, Human Reproductive Technologies and the Law, Vol. 1, HC 7-1, ISBN 0215023234. (Available to view at www.parliament.gov.uk or purchased in hard copy from TSO).
- C4 Human Reproductive Technologies and the Law: Government Response to the Report from the House of Commons Science and Technology Committee, Cm 6641, August 2005, ISBN 0101664125. (Available to view at www.parliament.gov.uk or purchased in hard copy from TSO).
- C5 Review of the Human Fertilisation and Embryology Act – A Public Consultation. Department of Health, August 2005, Ref 269640. (Available to view at www.dh.gov.uk/Consultations/ClosedConsultations or in hard copy (free of charge) from the DH Publications Orderline).
- C6 Report on the Consultation on the Review of the Human Fertilisation and Embryology Act 1990, prepared for Department of Health. People Science and Policy Ltd, March 2006. (Available to view via www.dh.gov.uk or in hard copy from the Department of Health at address overleaf.)

8 Also available with additional chapters as "A Question of Life" by Mary Warnock, Basil Blackwell Ltd, first published 1985.

Addresses

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