

Issue	Current HFE Act provisions	Comparisons to the Human Tissue Act	Impact of the EU Tissue Directive	Suggested Action/ Options	Comments
1. Statutory functions	<p>Section 8</p> <p>Monitor the field and advise Secretary of State upon request</p> <p>Publicise HFEA services and licensed activities</p> <p>Provide info to licence holders and patients</p>	<p>Section 12 Same as HFEA, plus:</p> <p>Maintaining a statement of general principle</p> <p>Providing general guidance and oversight</p> <p>Supervising compliance</p> <p>Explicit role of providing information to the 'public'</p>	<p>'Recitals' of Directive list the purpose and aim of legislation (free movement of tissues and cells, safeguarding patient safety)</p>	<p>1. Develop and list joint/ overlapping functions (including 'informing the <i>public</i>') <i>and</i></p> <p>2. Add separate functions for the 'HFEA part' of the new merged Authority which will replace the HFEA and the HTA (the merged Authority), possibly covering:</p> <ul style="list-style-type: none"> - protecting patient safety - insisting on centrality of informed consent - promoting best practice in and good regulation of the sector - including welfare of the child considerations in all decision making - ensuring public confidence in embryo research 	<p>HTA and HFEA have rather different background and remit</p> <p>Both concerned with ethical issues, but HFEA possibly more focussed on social issues too (in particular those concerning future generations)</p> <p>Tissue Directive far more concerned with 'health and safety':</p> <p>How can the loss of this 'ethics focus' be prevented in a much bigger, much more 'technical' regulator?</p>
2. Patient/ user focus	<p>Currently not a main focus of the legislation (apart from detailed consent provisions)</p>	<p>Again, not a strong focus of the new legislation</p>	<p>Isn't concerned with 'consumer' issues, apart from safety</p>	<p>Agreement that patients need to be placed more centrally - in HFEA's own decision making</p> <ul style="list-style-type: none"> -in assessing the sector's performance - and through better information/ public engagement work 	<p>Executive is preparing a patient strategy (communication department), but needs to be part of policy making and regulation too.</p> <p>Commitment to the patients' perspective might be made more visible through 'statutory functions'</p>
3. Definitions	<p>a) Lack of clarity</p>	<p>If a 'creation' falls</p>	<p>Would apply to</p>	<p>3 options:</p>	<p>a) and b) Advice on</p>

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a) embryo b) gamete c) treatment services	<p>whether embryos created through parthenogenesis, cloning etc are within the remit of the HFEA</p> <p>b) artificial gametes not heard of in 1990</p> <p>c) treatment services don't mention PGD/ embryo selection, vagueness of Schedule 2 paragraph 1 (d) ('suitable embryos')</p>	<p>outside the definition of an embryo, it might be considered 'tissue' which would still fall under the remit of the merged Authority.</p>	<p>creations considered to be embryos <i>and</i> everything else, but until merger with the HTA, different 'competent authorities' would be in charge</p>	<ol style="list-style-type: none"> 1. Rely on courts which seem to favour flexible reading of existing definitions 2. Develop new definitions (Parliamentary draftsmen) 3. Insert regulatory powers into legislation to bring new developments within its remit, even if not foreseen by the lawmakers (as has been done for 'research purposes') 	<p>'regulating embryos' and gametes is being prepared for the DH (through SCAG and ELC)</p> <p>c) PGD and PGD/HLA might benefit if clearly brought within the definition of treatment services</p>
4. Human animal chimeras Germ-line gene therapy				<p>Consider allowing research on chimaeras/germ-line gene therapy for research purposes.</p>	<p>Public opinion has to be taken into account. Promote public understanding of scientific rationale.</p>
5. GIFT and IUI	<p>Currently not within the remit of the HFEA (except possibly welfare of the child assessment in licensed centres)</p>	<p>n.a.</p>	<p>'Use of tissue or cells' – will require application of Directive</p>	<p>Develop proportionate regulatory response to IUI and/or GIFT, based on risk assessments</p>	<p>Bringing IUI and GIFT within the remit of the HFEA might considerably increase workload (without necessarily increased resources)</p> <p>Might lead to the closing down of smaller units</p> <p>So far, lack of clarity about numbers of units</p> <p>Simply extending definition of 'treatment services' to new</p>

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					techniques would mean all the regulatory requirements of the HFE Act would apply, which might not be appropriate
6. Internet providers, sperm sorting, etc	<p>HFE Act only covers 'treatment services'</p> <p>Internet providers often claim to simply 'introduce' donors to recipients, not to charge for the provision of gametes</p> <p>Sperm sorting does not require a licence (mere handling of gametes)</p>	n.a.	<p>Directive applies to any establishment handling or procuring tissues for use in humans, thus clearly applies to sperm sorting facilities</p> <p>Not clear whether internet providers are an 'establishment' in the meaning of the Directive</p>	<p>Not clear whether Directive regulations can be used to bring internet providers within HFEA's remit</p> <p>Possibly better addressed through (later) Review of the Act</p> <p>Explore implications for identifying donors – impossible to ensure donor identification unless regulated.</p>	<p>DH made it clear that they want internet and 'introductory' services to be brought under the remit of regulation, which means that a specific regulatory approach to internet services needs to be developed</p> <p>Difficulty of regulating the internet</p> <p>Would 'accrediting' sperm sorting under the Directive lend the practice an air of 'respectability'?</p> <p><i>Further research needed on how these services exactly operate</i></p>
7. Research	Schedule 2, paragraph 3 (1) gives the Authority explicit power to licence	HTA will deal with research institutions, but won't judge or	See HTA	HFEA needs to show commitment to 'better regulation agenda' (by avoiding duplications – for example with	The HFEA's involvement with research is unique. It is a function that won't be present in other aspects of the

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	<p>research</p> <p>Paragraph 3 (2) specifies lawful research purposes, also contains further regulation making power</p>	<p>licence particular research purposes</p>		<p>ethics committees - or unnecessary regulatory burdens – for example interim inspections), but needs to also stress how regulatory model has served research, and public confidence in research, well.</p>	<p>merged Authority's work and needs to be stressed.</p> <p>Public approval of embryo research is likely to be contingent on strict regulation.</p> <p>Paper on modernised research regulation processes will be taken to RegComm in early 2005</p>
8. Clinical trials	<p>HFEA cannot straightforwardly licence clinical trials. This makes it difficult to translate emerging knowledge into medical practice (cannot be done through research licence, as research embryos must not be used for treatment)</p>	<p>HTA will not be responsible for clinical trials</p>	<p>All use of tissue will fall under the directive, including clinical trials. But Directive not concerned with the aims or conduct of trials</p>	<p>Recommend provisions that enable the new regulator to issue trial licences</p>	<p>MRC/ HFEA working group has reported on its work on the introduction of new techniques into clinical practice and long-term follow-up</p> <p>Increased pressure for more structured introduction of new technologies and better data collection</p> <p>Difficulty for HFEA: political pressure to reduce burden of data collection is in tension with MRC recommendations to increase data collection</p>
9. Training licences	<p>No provision for 'training licences' in the HFE Act. This leads to difficulties in training practitioners (has to be done</p>	<p>Training explicitly exempt from HT Act consent requirements</p>	<p>All use of tissue will fall under the directive, including training. But Directive not concerned with the aims or conduct of trials</p>	<p>Recommend provisions that enable the new regulator to issue training licences</p> <p>Recommend to include provisions for training to be</p>	

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	through research licence)			allowed on poor quality and abnormally fertilised embryos which are not suitable for transfer and freezing for future use, subject to consent.	
10. Licensing PGD	<p>PGD licensing is done without explicit inclusion on the face of the Act</p> <p>Wide discretion for the Authority has been confirmed by the Court of Appeal</p>	n.a.	n.a.	It has been suggested that a clearer steer from Parliament on the legitimate uses of PGD technology might be welcome (similar to the regulation of research)	A Parliamentary (legislative) definition of legitimate uses of PGD would need to include further regulation making power (in order to keep up with developments) and would also still require the HFEA to decide whether difficult cases fit the legislative parameters (similar to current research licensing)
11. Welfare of the Child	Sections 13 (5) and 25 (2)	n.a.	Tissue Directive focuses on safety aspects of tissue use, no provisions on 'ethics'	<p>HFEA is conducting consultation on WoC guidance (not statutory provision)</p> <p>One possibility is that the requirement is moved into the statutory functions', which would show political commitment to 'welfare', but might enable a more practical/ flexible approach in its implementation (would also require HFEA 'to take account' of it, rather than just clinics!)</p>	Section 13 (5) seems inconsistent with evolving family law and human rights context, which makes enforcement and regulation difficult
12. Family law	Limits family law benefits (legal	n.a.	Directive does not cover family law	Agree clear use of consistent terminology ('donor') both in	

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consequences of ART	<p>parenthood) to heterosexual couples (who in the case of surrogacy need to be married)</p> <p>Section 28: 'treatment together'</p> <p>Section 30: parental orders (surrogacy)</p>		<p>outcomes of ART</p> <p>But: use of the term 'donor' might be inconsistent with understanding in ART (might become clearer through first technical Annex)</p>	<p>Directive regulations and in new Bill</p> <p>Argue that current family law provisions might be inconsistent with the evolving family law and human rights context</p>	
13. Deceased fathers and non-competent patients	<p>Section 28 (5B) (c) and section 1 of the HFE (Deceased Fathers) Act requires 'treatment together' before the man's death. In reality men undergoing cancer treatment might store their sperm without the woman having been seen or treated at the centre, but the woman is named on the consent form</p> <p>Schedule 3: lack of clarity whether parents can consent on behalf of their</p>	<p>HTA will be set up to deal specifically with consent to storage and use after a patient's death. But won't cover family law consequences</p>	<p>Technical Annex I makes provisions for deceased donors</p>	<ol style="list-style-type: none"> 1. Clarify 'treatment together' requirement. Also welfare of the child requirements 2. Sort out overlap with HTA remit – should HTA or HFEA deal with posthumous use? 3. Clarify possibility of consent by parent to storage for their children by implementing in full the recommendations of Professor McLean's report of 1998¹ 	<p>Parents can give consent for incompetent children's treatment in other areas of medicine.</p>

¹ Professor Sheila A M McLean (1998) *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*. She argues with regard to children (or persons who are temporarily incapacitated: "Where the individual is thought likely to recover, and the treatment will resulting sterility on recover, it is likely that it could be held to be in that person's best interest to be able, after treatment, to have the ability to choose whether or not to parent" (section 1.9).

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	incompetent children to the storage of gametes				
14. Register	<p>Section 31 obliges the HFEA to keep a register</p> <p>Statutory duty on clinics to report data is created through directions</p>	HT Bill does not create a register function	'Competent Authority' is under no direct obligation to maintain a register, but all materials and samples need to be fully traceable and identifiable	<p>Retain all functions but consider other ways of decreasing the data reporting burden on clinics</p> <p>Consider the possibilities for a 'slimmed down' register</p> <p>Impact-assess the future NHS wide data system for the role of the HFEA register</p>	<p>Providing information to offspring is one of the central functions of the HFEA and will have to be retained. Questions are being asked about the need to maintain such an extensive (and expensive) register, covering for example unsuccessful cycles (with dates, names etc)</p> <p>Brought into sharper focus through NICE guideline (higher costs to the NHS)</p> <p>But: recent MRC report argued for even more extensive data collection by the HFEA</p>
15. Confidentiality	Section 33 (1) – (3)	HTA not predicted to have an equivalent register function, no specific rules on confidentiality	Parent directive has some provisions for confidentiality (article 14)	Relax provisions on the disclosure by the Authority of confidential patient information to enable information sharing with other organisations and registers, and also the use of consultants, auditors and sub-contractors.	<p>There seems to be general agreement that the confidentiality requirements of the HFE Act need to be brought into line with wider medical law context</p> <p>There is also a specific problem regarding information sharing in antenatal care and in</p>

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					<p>particular Down's Syndrome screening for women after IVF or egg donation, because of the effect the hormonal stimulation regimes have on the serum level of the markers used to assess the risk of Down's syndrome.</p> <p>Child protection issues (existing children of patients) have also been mentioned – could a clinic alert authorities if they had concerns?</p>
<p>16. Opening of the register</p>	<p>Section 31 (4) establishes duty to disclose to applicants whether they are donor conceived</p> <p>HFEA Disclosure of Donor Information Regulation extend duty to disclose non-identifying (pre April 2005 children) and identifying information (post April 2005)</p> <p>But no provision for support, counselling and – crucially – financing these services</p>	n.a.	n.a.	<p>Take out requirement of 'intention to marry' and replace with 'intention to cohabit or to have children'</p> <p>Use Review of the Act to highlight that many additional services and structures need to be created to deal with the requirements created by opening the register</p> <p>Create clear and properly resourced responsibility for provision of counselling and mediation</p> <p>Define in legally binding form the information entitlements of donor offspring</p>	<p>Other matters that could be included in a reviewed Act (but would need to be legally and impact assessed):</p> <ul style="list-style-type: none"> - Access by the adult children/ offspring of donors to information about consanguinity in relation to someone they intend to marry (since their risk is equal to that of people conceived by donation) - Access by donor conceived people to information on the number of children conceived and therefore related to them as a result of donation (the 2004 Regulations only stipulate that applicants to the register may be told the number and sex of the

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					donor's own children) - Access to the same information by the adult children/offspring of donors
17. Pre-1990 records	Current HFE Act does not contain provisions on pre-Act records	n.a.	n.a.	Create clear responsibility for those holding records not to destroy them Discuss whether HFEA should become the body holding pre-Act records in the future	Making the HFEA responsible for pre-Act records (and for disclosing information contained in them) will have clear resource implications
18. Storage of records	Current HFE Act does not enable the explicit licensing of records storage	n.a.	n.a.	Creating a new type of licence for 'storage of records'	Ensuring safe and accessible storage of records is a problem where centres no longer operate. Creating 'record storage' licences would help with the historic audit, but could also put general record keeping onto a safer basis
19. Delegation	HFE Act does not allow the use of agencies or the delegation of functions (confidentiality restrictions)	Section 37 enables the HTA to delegate functions of the Authority to other authorities or offices (for example, the MHRA could take on inspection role)	Directive enables wide range of approaches to monitoring and inspection Delegation not excluded	Recommend provisions for delegation, while making an argument that keeping together the various functions of the HFEA is essential for its effectiveness	Confidentiality restrictions have been found an obstacle to employing contractors or consultants It is likely that new legislation will enable the merged Authority to delegate some of its functions Some representatives of professional bodies argue

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					<p>that HFEA should delegate its inspectorate function</p> <p>Need to delegate some functions to the Executive?</p>
<p>20. Licence Committees and licensing</p>	<p>Section 9, 10 and 11 Section 9 creates 'Licence Committees', consisting of Authority members</p> <p>Licence cannot exceed five years for treatment and storage (Sch 2, para 1 (5) and para 2 (3)) or 3 years for research (para 3 (9))</p>	<p>Section 13: No Licence Committees</p> <p>Executive takes on the role of licensing clinics and labs</p> <p>No prescriptions on the duration of the licence, or on inspection intervals</p>	<p>Directive does not make specific requirements about licensing. Various models of regulation are accommodated</p> <p>No maximum duration of licences (or on licences at all), but an inspection required every 2 years</p>	<p>Different models, with varying degrees of flexibility could be contained in new legislation</p> <p>It might be preferable to leave any detailed provisions on licensing systems out of the Bill itself This would enable the Authority to delegate much licensing work to the Executive</p> <p>Executive could deal with all 'routine' licence applications; decisions requiring 'policy work' first, might remain the responsibility of either a members based Licence Committee or the Authority as a whole</p>	<p>Respective roles of Authority and Executive in licensing have been under discussion</p> <p>The merged Authority will licence hundreds of premises, difficult to maintain licensing entirely based on Authority members</p> <p>Strengthening of the Executive's role in licensing has been found desirable by some, but licensing will require proper protocols and systems even if conducted by the Executive</p> <p>Authority could then also be a more credible reviews and appeals body</p>
<p>21. Appeals</p>	<p>Section 20: Different set of Authority members than made up the Licence Committee shall hear appeal (ss 3)</p>	<p>Section 16, 17 and 18 The Authority maintains appeals committee/s for the Executive's licensing decisions</p>	<p>As it stands, the Directive does not make provisions for appeals against the 'competent authority'</p> <p>This will be an issue for members states to pick up</p>	<p>Decisions about licensing systems (see above) determine nature of appeals process</p>	<p>Strengthening role of Executive in licensing decisions might lead to clearer Appeal structure, with Authority acting as an appeals body</p>

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<p>22. Accountability</p>	<p>HFEA (licensing) decisions are not substantially subject to review by an independent tribunal – High Court will only review ‘points of law’ (difficult to win cases against HFEA)</p>	<p>No independent review of decisions</p>	<p>See above</p>	<p>Having an independent tribunal process might clarify and bring to an end some prolonged disputes with clinics or applicants without necessarily going to the courts</p>	<p>Recently created regulators are subjected to scrutiny by an independent tribunal structure (for example CSCI)</p> <p>Politically it might also be useful to strengthen HFEA’s accountability towards Parliament (possibly through regular meetings) and its stakeholders (through agreed objectives or principles of regulation)</p>
<p>23. Inspections</p>	<p>Section 9 (8) prescribes annual inspections, unless a Licence Committee ‘considers an inspection in that year unnecessary’ (ss 9)</p> <p>Annual report to Licence Committee</p>	<p>Initially anticipated ‘Inspectorates’ were abolished (explicitly to enable smoother co-operation with the HFEA)</p> <p>No provisions on inspection intervals and duration of licences</p>	<p>Type and ‘intensity’ of inspections not specified (could be paper based?)</p> <p>Inspections at least every 2 years required by the Directive (article 7)</p>	<p>EU Directive necessitates some type of inspection every two years, but not necessarily in form of a visit</p> <p>Recommend fixed inspection/ visit intervals, but with in-built flexibility (earned independence)</p> <p><i>or</i></p> <p>Recommend open legislation that future regulator can execute flexibly</p> <p><i>also</i></p> <p>Introduce a duty to ‘co-operate’ with inspections – otherwise refusal to let inspectors onto premises is not per se enough</p>	<p>Open-ended or fixed term licences with fixed inspection intervals change the general balance of power between the sector and the regulator (whose duty is it to ensure compliance?)</p> <p>Taking a commitment to regular visits out of the Act might lead the Authority to defer inspections for the wrong reasons (i.e. not on the basis of a risk assessment, but simply because of staff shortages etc)</p>

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				to get an entry warrant	
24. Code of Practice	<p>Sections 25 and 26:</p> <p>Explicitly mentions</p> <ul style="list-style-type: none"> - Welfare of the child assessment - Need to consult before publication - Need for approval by the Secretary of State (who needs to lay before Parliament) 	<p>Sections 23 to 26:</p> <ul style="list-style-type: none"> - Need to review and re-issue regularly - Need to consult before publication - Flexible approach to the 'form' of the Code - <i>Core sections</i> of the Code need to be approved by the Secretary of State and lay before Parliament <p>DH based working group is currently developing a Code for the HTA</p>	<p>Directive will lift much of the content of the current HFEA CoP onto the level of legislation.</p> <p>CoP can go beyond requirements of the Directive, but not below.</p> <p>Less flexibility, since any changes to the content of Directive need to be agreed by all member states</p>	<p>Recommend more flexible approach to publication of the Code (taking account of need to consult and to get ministerial approval)</p> <p>Strengthen the role of professional bodies in developing/ taking responsibility for the more technical aspects of guidance</p>	<p>The Code is not very 'binding'.</p> <p>The Authority would like to be able to issue more binding guidance (for example directions)</p> <p>New, more 'updatable' and unified format for the Code has been discussed</p> <p>Strengthen links and information sharing between HTA Codes of Practice Working Group and HFEA</p>
25. Other guidance to clinics and labs	<p>Sections 23 and 24: 4 types of directions (reporting of information, transport and import and export of gametes and embryos)</p> <p>Schedule 2 para 1 (2), para 2 (2) and para 3 (7): right to impose licence restrictions</p>	<p>Section 20: no restriction on type of directions</p> <p>Schedule 3 para 5: Right to impose licence restrictions</p>	n.a.	<p>Recommend that Authority should be able to issue directions (binding) on a wider range of issues (for example donor anonymity or multiple embryo transfer)</p> <p>Turn Chair's or Chief Executive's letters into either amendments of the Code of Practice or into directions to avoid lack of clarity where they 'sit' in the regulatory framework</p>	<p>Currently the relationship between different types of guidance is not always clear (Code, Chief Executive's letters, Chair's letters)</p> <p>New Code of Practice format (online, live, updatable, searchable) could enable the regular bringing together of all types of guidance to clinics</p>

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	<p>Authority also issues Chair's and Chief Executive's Letters which don't need to be consulted upon</p> <p>No further regulation making powers</p>	<p>Schedule 2 para 21 gives power to Minister to confer further regulation making power to the HTA</p>		<p>Recommend further regulation making powers, similar to current research purposes provisions (for example regarding new ways of creating embryos)</p>	
<p>26. Accreditation/ professional guidance/ self regulation</p>	<p>Current legislation contains no formal provisions on the relationship between HFEA and professional guidance, but based on the general assumption that professional self-regulation is not sufficient</p> <p>However that does not preclude self 'assessment' as part of an HFEA-run inspection process</p>	<p>HTA too created in response to perceived weaknesses in self-regulation (Alder Hey, Bristol)</p>	<p>Directive is non-prescriptive in the type of regulatory model it imposes, but many technical requirements that might currently be considered the responsibility of professional bodies will be contained in legislation itself (quality assurance etc)</p> <p>Considerable tension between impact of Directive and wider moves towards more flexible regulation (Better Regulation Task Force)</p>	<p>Combine discussions on professional guidelines/ accreditation etc with the wider work on Review of the Act and EU Tissue Directive</p> <p>Strengthen involvement of professional bodies through involving them very directly in developing Code of Practice and local quality management systems</p> <p>Maintain strong role for an independent regulator in setting national, evidence based, patient focussed standards</p>	<p>Professional bodies are pushing for a changed relationship between 'their' guidance and 'our' inspections (see Select Committee Hearing on 8 December 2004).</p> <p>DH has indicated that they are interested in a more 'light touch' approach to regulation, in which self-regulation or accreditation might play a role</p>
<p>27. Person Responsible</p>	<p>Section 17: PR must secure that colleagues are 'of such character and are so qualified by training and</p>	<p>Section 17 and 18: "Designated individual" has similar role to PR, but less prescriptive</p>	<p>Directive creates 'Responsible Person' (article 17)</p> <p>Requirement of biomedical qualification</p>	<p>Language and role needs to be unified in new legislation</p> <p>Recommend strengthening of the unique role of 'PR' – selection, training, commitment</p>	<p>The regulation team have argued for a strengthening of the PR's role and responsibilities</p> <p>Role of PR (and</p>

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	experience' to be suitable and that 'suitable practices' are used	about 'suitable' colleagues, and no mentioning of 'proper equipment' and 'proper arrangements' for keeping and disposal	Stronger focus on the 'establishment' than on persons or activities	to compliance Imposing criminal liability on PR for breaches of the Act has no equivalent in the NHS – recommend that this should be removed.	qualifications) is outlined in Tissue Directive. In considering the question of penalties, the DH may wish to consider the case for sanctions against coerced gamete donation, e.g. junior staff in clinics having to donate gametes for research.
28. Nominal licensee	Role of 'nominal licensee' separate to that of PR but not a requirement. Only nominal licensee can vary licence to designate different PR.	Licence is held by 'designated individual' who can also designate other suitable persons to carry out licensed activity. Licensable activities can still be carried out where licence has ceased to have effect and before directions are issued (Section 24 (5)).	See above.	1. Make appointment of nominal licensee a legal requirement 2. Nominal licensee should have senior management role to fit with clinical governance system (or role could be held by the NHS Trust or other body, as is sometimes the case already)	Not having a separate nominal licensee can present problems, e.g. if an accident befalls the person responsible, the licence has to be revoked.
29. Focus on quality assurance and risk management in clinics	Currently not part of the formal legislative framework, but being pursued through the regulation modernisation agenda	Regulatory approach not specified in the Bill, but technical issues are less central to HT Act	Standard Operating Procedures and overall Quality Management Systems central to the Directive's approach	Focus on quality and safety can be pursued without changes to the wording of the legislation But is it preferable to 1. Clarify regulatory approach or to 2. Leave approach unspecified	New focus on quality management will require changes in the sector and the way inspections are conducted

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				(and therefore flexible)?	
30. Sanctions	<p>Section 41 contains offences and sanctions</p> <p>Breaking the Code is not per se an offence (section 25 (6))</p> <p>The only sanctions available for breaches of guidance are: putting conditions on a licence, varying, suspending or revoking a licence (if conditions set out in s.18 are met)</p>	<p>Section 22: Carrying out licensable activities without a licence is an offence</p> <p>Breaking the Code is not necessarily an offence (section 25)</p> <p>The only sanctions available for breaches are: putting conditions on a licence, suspending, varying or revoking it</p>	Directive leaves sanctions to the member states, i.e. DH regulations will specify sanctions for breaches of the Directive	<p>Expand range of currently available sanctions to include fines/ charging non-compliant clinics for the increased cost of regulation</p> <p>Recommend that 'Directive sanctions' should be kept in line with current HFEA/ HTA sanctions</p>	<p>Currently the sanctions are felt to be at times too draconian (revocation) or too lenient (conditions)</p> <p>Range of sanction might include fines, but also 'naming and shaming' or requiring clinics to inform patients of negative findings</p> <p>It would also be useful to enable the regulator to charge non-compliant clinics for the costs they incur through more intense regulation</p> <p>Review issue of criminal responsibility (also see under Person Responsible).</p>
31. Statutory storage periods	<p>Currently contained in DH regulations</p> <p>Complicated schedule allows extensions (beyond 5 or 10 years), but not in the cases of donation or surrogacy</p>	n.a.	<p>Regulation of storage periods were changed after HFEA intervention</p> <p>Details yet to emerge</p>	<p>Recommend that DH review storage periods as part of the wider review of the Act</p> <p>Recommend that the content of the regulation is transferred to the new legislative framework or is to be placed in a new Code of Practice</p> <p>Simplify regulation and tailor to evidence based risk assessments</p>	SEED Review mentions storage periods as a matter for the DH

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<p>32. Financial aspects of clinics' work</p>	<p>Currently, HFEA does have no powers to monitor or publish clinics' financial performance or pricing structure or to demand the reporting of data</p> <p>The only exception to this rule is that the Authority sets a maximum payment for gamete donors (£15)</p>	<p>HTA's role does not extend to the financial aspects of clinics' or labs' work</p> <p>Most licensed premises will be part of the NHS or universities, so the role of private premises is much smaller</p>	<p>Directive imposes principle that procurement must be not-for-profit</p> <p>Allows compensation for donors, if member states can show need</p>	<p>HFEA cannot regulate pricing, but maybe could recommend that clinics must report prices to HFEA with a view to publication</p> <p>Possibly also introduce duty for clinics to submit audited accounts to the HFEA (but: difficulty to define 'treatment cycle' for the purposes of comparing pricing)</p>	<p>The Audit and Regulation Teams have argued that powers should be extended to assess clinics' financial soundness, since it can have negative impacts on patient care</p> <p>But resource and capacity implications if HFEA asks for this data</p> <p>If the merged Authority's remit extends to financial aspects of clinics' work it would have an unprecedented width of responsibilities</p> <p>Financial and advertising aspects of treatments are often most pressing concern for patients (and cause of many complaints)</p>
<p>33. Complaints</p>	<p>HFEA has taken on role of dealing with patient complaints – not directly included in the HFE Act</p> <p>HFEA does not adjudicate, but uses complaints as evidence for inspections and</p>	<p>HT Bill does not make provisions for complaints from patients or relatives</p>	<p>'Competent Authority' does not have an explicit complaints function</p>	<p>Flag up to DH that private patients are often unable to voice their complaints in a structured system</p>	<p>NHS complaints structures very developed</p> <p>But no developed complaints systems in the private sector</p> <p>Complaints now used to facilitate learning in the sector</p>

Issue	Current HFE Act provisions	Comparisons to the Human Tissue Act	Impact of the EU Tissue Directive	Suggested Action/ Options	Comments
	licensing				
34. Culture media	Culture media are outside the remit of the HFE Act	Production of culture media might involve handling human tissues – HTA might be responsible for some aspects of this	Culture media only 'caught' by the Directive from a safety angle (transmission risk), not: efficacy, developing optimised culture media	Need to flag up to DH that there might be risks inherent in and concerns about culture media that aren't currently picked up by any regulator	