REVIEW OF THE HUMAN FERTILISATION & EMBRYOLOGY ACT:
A PUBLIC CONSULTATION.
DEPARTMENT OF HEALTH 2005

This pro forma repeats all of the questions and proposals in the above titled consultation document. The boxes below will expand as you type. When completed it should be e-mailed to review-hfe-act@dh.gsi.gov.uk

The closing date for responses is Friday 25 November.

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Questions and proposals for consultation

The model and scope of regulation

1. The Government believes that both the development and use of human reproductive technologies, and their regulation in response to public concerns, should continue to be subject to legislation. (Paragraph 2.7).

The Academy supports this view. There is an obligation of Government and its delegated regulatory bodies to make treatment safe, efficient and cost effective.

2. On balance, the Government believes that the current model of regulation, whereby Parliament sets the prohibitions and parameters within which an independent statutory authority licenses activities, has worked well and should continue. (Paragraph 2.14).

The Academy supports the Government's view on the current model of regulation. However, the nature of legislation needs to be carefully considered and should allow scope for scientific advance without the need to come back to Parliament at regular intervals.

3. However, the Government also accepts that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law. In

particular, the Government accepts the need to clarify the extent of any policy-making role of the regulator. (Paragraph 2.15).

Agreed. The regulator needs to be sufficiently broadly constituted to provide publicly acceptable decisions, and to have sufficient powers to regulate, and to enforce the Code of Practice and the Act. If a new Body is created that covers a wider remit than it is competent to handle, clarification of the extent of its policy-making role would be needed.

4. The Government believes that legislation should make clear that all human embryos outside the body are within the scope of regulation and subject to the control of the statutory licensing authority regardless of the manner of their creation. (Paragraph 2.20).

Agreed. However, the definition of human embryo needs to be sufficiently flexible to allow for other types of embryo research where fertilisation does not occur, such as parthenogenetic embryos, or where cell nuclear replacement has made use of enucleated oocytes from other species, etc.

5. The Government considers that the best approach is to define the forms of embryo which may be placed in a woman and in what circumstances, and to regulate other forms of embryo insofar as these are created and used for research. (Paragraph 2.22).

Agreed.

6. The Government proposes that eggs undergoing processes intended to result in the creation of embryos – whether fertilisation or other non-fertilisation processes – should continue to be subject to regulation. (Paragraph 2.27).

Agreed.

7. The Government believes that the potential use of artificial gametes raises safety issues and that some uses may also raise ethical concerns. Therefore the Government proposes that the use of artificial gametes in assisted reproduction treatment should not be permitted but that the HFE Act should contain a regulation-making power giving Parliament more flexibility to allow the use of artificial gametes in future should it wish to do so. (Paragraph 2.31).

Agreed, but it is important that research on artificial gametes is permitted.

8. The Government seeks views on the extent to which regulation should apply to the use of a couple's "fresh" gametes. Should this be limited to technical and safety issues only or should treatment involving a couple's fresh gametes be subject to the full requirements of the HFE Act where these are relevant? (Paragraph 2.37).

The Code of Practice could include details of an approach to be used in these

circumstances. As the Code of Practice has been subject to the full force of the authority of the HFEA, it is not necessary for such a subject to be included in the Act.

9. The Government intends to make the operation of internet services which involve the supply of gametes subject to regulation. Should the law (a) prohibit the operation of such services, (b) regulate the safety and quality aspects of such services, (c) regulate safety and quality and remove any anomalies with other methods of gamete donation? (Paragraph 2.42).

The Academy cannot present a consensus answer.

10. The Government seeks views on whether moving toward the transfer of a single embryo during a treatment cycle should (a) be a matter for legislation, (b) be a matter for the regulator, (c) be a matter for the professional bodies only. (Paragraph 2.47).

This should be a matter for professional bodies, but the regulator should have a role in supervision of the practice.

11. The Government invites views on what, if any, powers the regulator should have in relation to the costs of assisted reproduction treatments provided to private patients. (Paragraph 2.49).

Powers should be available to the regulator. It is reasonable to require clinics to publish a clear unambiguous list of procedures and charges. Advice on real costs of treatments and of comparisons of charges at different clinics would be useful.

12. The Government invites comments on the desirability of making the regulator's licensing powers more flexible, for instance (a) the ability to licence clinical trials, and (b) explicitly allow training of clinicians and researchers. (Paragraph 2.56).

The licensing powers need to be more flexible and to take account of the need for clinical trials and for training.

<u>Welfare of the child</u>

13. The Government seeks views on whether taking account of the welfare of the child who may be born as a result of treatment and any other child who may be affected should remain an HFE Act *obligation* on persons providing treatment services. (Paragraph 3.19).

Taking account of the welfare of the child should remain an HFE Act obligation on persons providing treatment services. This obligation has led to the creation of a high standard of care in most but not all clinics. However, the Academy stresses that it is the responsibility of everyone concerned, including parents, to avoid harm to the child and generally to take account of the child's welfare.

14. The Government seeks views on whether, if a welfare of the child requirement remains in the HFE Act, compliance with it should be a matter for "good medical practice" and the clinician's judgement, rather than be subject to HFEA guidance and regulation. (Paragraph 3.23).

It should be by good medical practice and the clinician's judgement, with advice from the HFEA as to the safety and success rate of treatments.

15. If you agree with this, do you think that clinicians should only be required by the legislation to take account of the *medical* welfare of the child? (Paragraph 3.24).

Clinicians should be required to take account of both medical and social welfare of the child.

16. If a legal obligation to consider the welfare of the child is retained, should it be reformulated to refer to a risk of serious harm? For example, should it specify that treatment should not be provided where the clinician believes there is risk of significant harm? (Paragraph 3.26).

The Academy considers that 'serious' or 'significant' harm may be difficult to define so should not be specified. The Academy considers 'welfare' to be a broader and more flexible term.

17. Do you think that the requirement to take account of "the need of the child for a father", as part of considering the welfare of the child, should be removed from the Act? Alternatively, do you think that it should be replaced with "the need of the child for a father and a mother"? (Paragraph 3.32).

The Academy cannot present a consensus answer.

<u>The use and storage of gametes and embryos</u>

18. The Government believes that on balance, the HFE Act's existing requirements for written consent remain proportionate and appropriate, and provide a valuable protection of the wishes of patients and donors. Do you agree? (Paragraph 4.10).

Agreed.

19. Should the requirement for *written* consent be extended to apply to all assisted conception treatments provided in licensed clinics, including treatment using a couple's own 'fresh' gametes such as IUI and GIFT? (Paragraph 4.11).

Yes, written consent should be required for all assisted conception treatments provided in licensed clinics.

20. The Government proposes that the law should allow the *storage* of gametes without the consent of a person lacking capacity where the gametes were lawfully removed. Do you agree? (Paragraph 4.16).

Agreed.

21. The Government proposes that a person's gametes stored in these circumstances may only be *used* with the consent of that person. Do you agree? (Paragraph 4.17).

Agreed. This would require written documentation before illness supervenes.

22. The Government invites views on whether the law should be changed to require the withdrawal of the consent of *both* parties whose gametes were used to create an embryo in order to allow a stored embryo to perish, and that such an embryo should otherwise continue in storage until the statutory maximum storage period is reached. (Paragraph 4.21).

Agreed. Both parties' consent should be needed to allow a stored embryo to perish.

23. Do you think that the law should continue to set statutory maximum storage periods for gametes and embryos and if so how should these be determined? (Paragraph 4.25).

The Academy agrees that the law should continue to set statutory maximum storage periods. A 10-year maximum storage period for both gametes and embryos, with a 5-year review and possible extensions in exceptional circumstances, is favoured.

24. If you think that the law should continue to set statutory maximum storage limits, should the storage limits for donation be brought into line with the storage periods for treatment? (Paragraph 4.26).

The Academy cannot provide a consensus answer, however there is support for increasing the storage limits for donation.

25. The Government invites views on whether the requirement on licensed centres to provide "such relevant information as is proper" should remain a legal requirement. (Paragraph 4.35).

Relevant information is important and should remain a legal requirement.

26. If so, should that requirement be extended to require clinics to be specific about which treatments they provide are outside the National Institute for Clinical Excellence's clinical guideline on infertility treatment? (Paragraph 4.36).

The Academy considers it reasonable to expect clinics to be specific about which treatments they provide, but believes this to be a matter for professional self-regulation.

27. The Government invites views on whether the requirement on licensed centres to offer a suitable opportunity to receive counselling should remain a legal obligation. (Paragraph 4.40).

Counselling should remain a legal obligation, and is particularly important with respect to donation.

28. Alternatively, should the legal requirement to offer a suitable opportunity to receive counselling apply only in the case of treatment involving donated gametes and embryos? (Paragraph 4.41).

No, counselling should remain a legal obligation.

29. The Government invites views on whether the appropriate level of compensation for donors should be set by the regulator or by Parliament by means of regulations, rather than by the HFEA as now. (Paragraph 4.45).

The Academy considers that the HFEA is better placed to decide on the details.

30. The Government invites views on whether payments for the supply of gametes (other than compensation for expenses or inconvenience) should be prohibited in all circumstances, including research that is currently outside the scope of the HFE Act. (Paragraph 4.47).

Payment for the supply of gametes (other than compensation for expenses or inconvenience) should be prohibited in all circumstances.

<u>Reproductive choices: screening and selection</u>

31. The Government invites views on whether legislation should set out the general criteria under which embryo screening and selection can be undertaken. If so, what should those general criteria be? (Paragraph 5.19).

The Academy considers that screening should be the responsibility of the professional societies. They should make recommendations in accordance with the best information available.

32. Do you think that there should be a prohibition on deliberately screening *in,* or selecting *for* impairments and disabilities – as opposed to screening *out*, or selecting against? (Paragraph 5.20).

The Academy supports a prohibition.

33. Should the particular uses of embryo screening and selection remain a matter for decision and licensing by a statutory regulator in accordance with the general criteria set by Parliament? (Paragraph 5.21).

The Academy encountered differences of opinion among its Fellows as to whether legislation is required, and the relative roles of the regulator versus patients together with clinicians. The Academy considers that these decisions should largely be left to patients, clinicians and local ethical review, but with general uses of embryo screening a matter for guidance by a statutory regulator with appropriate genetics experience. The conditions for which screening could be carried out will increase, therefore Parliament should not create lists of diseases which may become quickly out of date.

34. Alternatively, should the particular uses of embryo screening and selection be a matter for patients and clinicians, within the legal limits set by Parliament? (Paragraph 5.22).

See answer above. The particular uses of embryo screening and selection should be a matter for patients and clinicians within the legal limits set by parliament and monitored by the regulator.

35. What are your views on the regulation of PGD with tissue typing? Should the legislation set out criteria under which this should be allowed? If so what should they be? Beyond that should particular uses need to be approved by the regulator – or should patients with their clinicians be free to make their own decisions? (Paragraph 5.23).

Decisions on PGD with tissue-typing should be left to families and their doctors, within guidelines established by Parliament and monitored by the regulator.

36. The Government invites views on what statutory controls, if any, should apply to the screening and selection of gametes. (Paragraph 5.27).

These should be specified by the professional societies and be under the control of a regulator.

37. The Government seeks views on sex selection for non-medical reasons. In particular, should this be banned? Or should people be allowed to use sex selection techniques for family balancing purposes as the Science and Technology Committee suggest? If so, how many children of one gender should a couple already have before being allowed to use sex selection techniques to try for a child of the other gender? (Paragraph 5.32).

The Academy cannot provide a consensus answer.

38. The Government proposes that the prohibition in the HFE Act on genetic modification of embryos for reproductive purposes should continue and be

extended to gametes used in treatment. We invite views as to whether the legislation should include a power for Parliament to relax this ban through regulations (rather than primary legislation) if assured of safety and efficacy. (Paragraph 5.38).

The Academy considers that the ban on genetic modification of embryos for reproductive purposes should remain, at least for the present. However, there should be legislation with the power to relax this ban through regulations, if necessary.

Information and the HFEA Register

39. The Government believes that it is essential to maintain a central register of donor treatment to which donor-conceived people can have access for information about their donor, and to find out if they are related to someone they intend to marry. Do you agree? (Paragraph 6.14).

Agreed.

40. The Government invites views on whether people should be able to obtain information about whether they were donor-conceived and about their donor (including identifying information where lawful) from the age of 16 rather than, as now, from the age of 18. (Paragraph 6.18).

The Academy considers that the age limit should be set at 16 rather than 18.

41. The Government proposes to enable donor-conceived people to access information to discover whether they are related to someone with whom they intend to form a civil partnership, and would welcome comments. (Paragraph 6.20).

Agreed.

42. The Government invites views on whether the law should specify what non-identifying information about offspring can be released to gamete and embryo donors. (Paragraph 6.23).

The Academy considers that any non-identifying information to be released to donors should be specified in law, and should be very limited.

43. The Government seeks views on whether donor-conceived people should be able to access information about their donor-conceived siblings (where applicable). If so should this be limited to non-identifying information? (Paragraph 6.25).

Information about siblings should not be accessible.

44. Should the natural children of donors be able to access information about their donor-conceived siblings (where applicable) and vice-versa? If so should this be limited to non-identifying information? (Paragraph 6.26).

Information about siblings should not be accessible.

45. The Government seeks views on what measures would be appropriate, if any, to ensure that parents tell children conceived through gamete or embryo donation that they are donor-conceived? (Paragraph 6.31).

Parents should be strongly encouraged, but not forced, to tell children about their origins.

46. The Government invites views on whether, in future, the HFEA's data register should continue to record and publish information on all licensed treatments including outcome data (where it is satisfied that they are not misleading). (Paragraph 6.39).

The Academy considers that the data register should continue to record and publish, as openly as possible, information on all licensed treatments and their outcome. However, there is concern that the HFEA has inhibited careful analysis on the grounds of confidentiality and it may be appropriate that this data collection and publication should be given to others.

47. If the HFEA's data register is to continue to collect information on all licensed treatments, should the dataset be expanded to facilitate more effective follow-up research? (Paragraph 6.40).

The dataset should be expanded if possible to include follow-up data.

48. Alternatively, if the HFEA's data register is to be restricted to information on licensed treatments involving donated gametes or embryos, should licensed clinics be required to maintain local databases of additional information for research? (Paragraph 6.41).

Local registers may be useful, but a central register could fulfil a defined purpose.

49. The Government proposes that the confidentiality provisions of the HFE Act should be revised so that information about assisted reproduction treatment is treated in the same way as other medical information and subject to the same safeguards. Do you agree? (Paragraph 6.44).

The confidentiality provisions of the HFE Act should be revised. The Academy considers that the confidentiality restrictions have been inhibitory and should be brought into line with all other medical data.

<u>Surrogacy</u>

50. The Government invites views on what, if any, changes are needed to the law and regulation as it relates to surrogacy. (Paragraph 7.17).

The surrogacy laws and regulations should be revised, either as part of the HFE Act, or by separate legislation.

51. If changes to the law and regulation on surrogacy are necessary, do the recommendations of the 'Brazier Report' represent the best way forward? (Paragraph 7.18).

Yes, the recommendations in the Brazier Report should be implemented.

52. If changes to the law and regulation on surrogacy are necessary, should they be taken forward as part of the review of the HFE Act, or in separate legislation? (Paragraph 7.19).

The Academy cannot provide a consensus answer.

<u>Status and legal parenthood</u>

53. The Government invites views as to whether the HFE Act should treat an unmarried man as the father of a child resulting from treatment in the same way it treats a married man. If so, how would this be achieved given that there is no legal definition of an unmarried couple? (Paragraph 8.16).

The Academy considers that a couple's consent in writing to being "treated together" is the most appropriate indicator of parenthood, for both single-sex and heterosexual couples. Academy Fellows expressed mixed views about whether an unmarried man should be treated by the Act in the same way as a married man.

54. Should a court be able to make a parental order in favour of unmarried as well as married couples in surrogacy cases? (Paragraph 8.18).

The Academy cannot provide a consensus answer.

55. The Government seeks views on whether:
• a court should be able to make a parental order (following surrogacy) in favour of civil partners, subject to the same rules and requirements that apply to married couples
• where one of the civil partners carries a child as the result of assisted reproduction treatment, the other civil partner should be treated in law as the parent of the child in line with married couples. (Paragraph 8.22).

Yes to both parts. The Academy considers that a couple's consent in writing to being "treated together" is the most appropriate indicator of parenthood.

56. The Government seeks views on whether the status and legal parenthood provisions in the HFE Act should apply to same-sex couples who *do not* form a civil partnership. If so, how would any automatic recognition of parenthood be achieved given the lack of legal ties between the couple? (Paragraph 8.24).

Yes. The Academy considers that a couple's consent in writing to being "treated together" is the most appropriate indicator of parenthood for same-sex couples.

Research

57. In common with the Science and Technology Committee, the Government believes that there is no case at present for either an extension or a reduction to the 14 day time limit for keeping an embryo. Any change would remain a matter for Parliament. (Paragraph 9.15).

Agreed.

58. The Government believes that research undertaken on embryos using the cell nuclear replacement technique for the purpose of studying mitochondrial diseases should be permissible in law, subject to licensing. (Paragraph 9.22).

Agreed, subject to licensing.

59. Further, the Government invites views on removing the current prohibition on "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" for research purposes, subject to licensing. (Paragraph 9.23).

The prohibition should be removed for research purposes only, at least for the present time. Much important information may well be obtained about cellular function that could be of future importance.

60. The Government invites views on whether the law should permit altering the genetic structure of an embryo for research purposes, subject to licensing. (Paragraph 9.28).

Altering the genetic structure of an embryo should be allowed for research purposes, but only subject to licensing and under very strict regulation.

61. The Government invites views on whether the law should permit the creation of human-animal hybrid or chimera embryos for research purposes only (subject to the limit of 14 days culture in vitro, after which the embryos would have to be destroyed). (Paragraph 9.35).

The Academy considers that this should be permitted. Research on human-animal chimeras and hybrids is scientifically important, but should be carried out

under closely defined and monitored situations. The Academy is concerned that the 14 day limit is not appropriate for many scientific contexts, e.g. for in vitro cultures which will never develop sufficient complexity to be of concern; for animal embryos carrying a small proportion of human cells or where the human cells are confined to a specific system. The Academy is concerned that important research tools, such as the recent derivation of mice carrying human chromosome 21 as a model for Down's Syndrome, might fall foul of this regulation.

62. The Government invites views on whether the current list of legitimate purposes for licensed research involving embryos remains appropriate. (Paragraph 9.38).

The Academy considers that the list of purposes for which human embryo research can be licensed is appropriate.

63. The Government believes that the purposes for which research using embryos may legitimately be undertaken should, as now, be defined in law and research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight. (Paragraph 9.41).

The purposes for which research using embryos may legitimately be undertaken should continue to be defined in law, with research projects subject to approval by a national body. Ethical and academic considerations must be judged by appropriately experienced people. However, mechanisms should be adopted to reduce bureaucracy and delay.

64. The Government invites views on what, if any, additional regulatory requirements should apply to the procurement and use of gametes for purposes of research. (Paragraph 9.45).

The Academy considers that there is little need for any additional regulatory requirements for gametes that are to be used in research.

65. The Government invites comments on the desirability of allowing the creation of embryos for the *treatment* of serious diseases (as distinct from *research* into developing treatments for serious diseases which is already allowed). (Paragraph 9.47).

The Academy considers that, if research involving the creation of embryos for the treatment of serious diseases shows possible therapeutic benefit, it is illogical to disallow the use of the therapy. However, this should be preceded by widespread debate and discussion to explore safety issues, to ensure that there were no other alternatives, and to allay public anxiety. Strict regulation would be required.

<u>The Regulatory Authority for Tissues and Embryos</u>

66. The Government proposes that RATE, in common with the HFEA and HTA, will be headed by a lay chairperson, and have substantial lay representation among its membership. The membership will also need to have, or have access to, sufficient medical and scientific expertise in relation to the activities that come within its remit. (Paragraph 10.4).

The Academy is concerned that, in the interests of reducing the number of 'arm's length' bodies, government may be destroying a body (HFEA) that has developed with quite remarkable success in a very difficult and sensitive area. The field is advancing so quickly that new issues with ethical and far-reaching implications for both patients and society will require all the experience, wisdom and sensitivity that can be mustered. The remit of a combined HTA and HFEA is huge. The HFEA alone struggled to keep up with a remit restricted to reproductive technologies, and was often criticized for not being broad enough to deal with all relevant issues. A combined authority with substantially lay representation cannot cover the many areas involved, without a panel of subcommittees of specific experts, which would be likely to make RATE a very large and unwieldy regulator.
However, if the merger has to go ahead, the Academy approves the steps proposed by the Government. It is important that there is sufficient representation of medical and scientific expertise for the body to be knowledgeable and effective.

67. The Government proposes that:
• RATE will be an executive non-departmental public body. Its primary function will be to consider applications for licences to undertake those activities which Parliament decides should be subject to licensing. It will be funded principally from fees levied on licence-holders
• RATE will be responsible for regular inspections of premises where licensable activities are carried on.
• RATE will issue codes of practice giving guidance to persons undertaking those activities within its remit
• RATE will maintain a central database of, at least, information relating to the use of donated gametes and embryos, and children born as a result.
(Paragraph 10.5).

The Academy approves the steps proposed by the Government.
The Academy as a member of the UK Clinical Research Collaboration (UKCRC), also fully supports the response and recommendations submitted by the UKCRC on the development and administration of RATE.

68. Both the HFEA and the HTA currently have statutory functions including to monitor or review developments relating to the activities within their remits, and to provide advice to the Secretary of State where appropriate or where asked to do so. The Government believes that a similar 'advisory' function would be appropriate for RATE as this body will be well placed to observe and monitor

developments through its licensing and inspection procedures and its information gathering function. (Paragraph 10.6).

Agreed, but RATE should also seek advice intermittently from the professional bodies as to what should be considered.

69. The Government proposes that:
• the chairperson and members of RATE will be appointed by the NHS Appointments Commission
• RATE will publish an annual report, which must be laid before Parliament
• legislation will set out requirements for consultation and approval of codes of practice
• RATE will publish summaries of embryo research licence applications received. (Paragraph 10.7).

The Academy supports these proposals.

70. The Government invites views on whether legislation should define a formal role for the professional bodies in advising RATE on the content of technical standards for assisted reproduction and embryo research. (Paragraph 10.10).

A formal role for the professional bodies would be appropriate, since they are already setting high standards for their members through evidence-based guidelines and protocols.

71. The Government invites views on what sanctions should be available to the regulator to ensure compliance whilst promoting service improvement. (Paragraph 10.13).

A range of sanctions should be available to the regulator, including suspension of the licence until compliance is established.

72. The Government invites views on whether the maximum penalty of ten years imprisonment under the HFE Act should be altered, and if so, what should the maximum penalty be? (Paragraph 10.16).

The Academy considers that a maximum penalty of 10 years' imprisonment is unduly harsh, and should be reduced.

<u>Miscellaneous</u>

73. The Government invites views on the extent to which the principles of good regulation are upheld in the Government's proposals, and any other comments or information about the regulatory impact of the measures described in this consultation document. (Paragraph R1.16).

The Academy has some comments on the wording of the consultation document:

1. In paragraph 2.13:
    a. The statement that the quality of infertility treatments has been maintained at a sufficiently high level across all clinics is questionable. For instance, there is evidence of variability in rates of development of embryos to the blastocyst stage in vitro, which has consequences for successful pregnancies.
    b. “Flourish” is an exaggeration.

2. In definitions of “embryo” it is helpful to qualify the word in all cases, e.g. preimplantation embryo, postimplantation embryo, parthenogenetic embryo, 2-cell embryo, etc. Also, much later stage embryos that have miscarried or have been terminated do not fall under the scope of the HFEA, although their use in research may be covered by the EU Tissue Directive.

3. In paragraph 2.23: Care needs to be taken with respect to definitions of “fertilisation”, to ensure that they encompass ICSI (intracytoplasmic sperm injection), which can use mature sperm of immature, spermatid stages. Also, the idea of nuclear transplantation (after fertilisation) to overcome problems of embryo viability due to mitochondrial diseases, needs to be considered. Furthermore, it would be possible in theory to reconstitute an embryo with one male and one female pronucleus, where the former has either come from a fertilised egg or after ICSI and the latter from a parthenogenetically activated oocyte.

4. In paragraph 2.24: A “unique genetic identity” is essentially established after the first meiotic division, as recombination will have occurred. As above, parthenogenetic embryos should be included in the Act. Although they will not give rise to liveborn offspring, it is likely that some will develop beyond 14 dpc.

5. In paragraph 2.29: It has been shown in mice that effectively dead, freeze-dried sperm can be used for ICSI and give apparently normal live born animals. Perhaps the word “live” should therefore be omitted from any definition.

6. In paragraph 2.30: Oocytes are never truly haploid, as the second meiotic division and polar body extrusion are not completed until after fertilisation.

74. Finally, we would welcome your views on any other issues that you feel should be considered or changes that you would like to see made to the HFE Act 1990.

THANK YOU