

The cloning of animals from adult cells : fourth report / Science and Technology Committee.

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SCIENCE AND TECHNOLOGY COMMITTEE

Fourth Report

**THE CLONING OF ANIMALS FROM ADULT
CELLS**

Report and Proceedings of the Committee

*Ordered by The House of Commons to be printed
28 July 1998*

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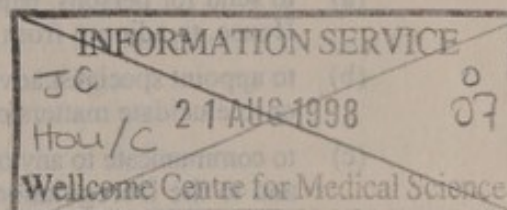
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SCIENCE AND TECHNOLOGY COMMITTEE

Fourth Report



Cloning

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THE CLONING OF ANIMALS FROM ADULT CELLS

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The Science and Technology Committee is appointed under Standing Order No. 152 to examine the expenditure, administration and policy of the Office of Science and Technology and associated public bodies.

The Committee consists of 11 Members. It has a quorum of three. Unless the House otherwise orders, all Members nominated to the Committee continue to be Members of it for the remainder of the Parliament.

The Committee has power:

- (a) to send for persons, papers and records, to sit notwithstanding any adjournment of the House, to adjourn from place to place, and to report from time to time;
- (b) to appoint specialist advisers either to supply information which is not readily available or to elucidate matters of complexity within the Committee's order of reference;
- (c) to communicate to any other such committee and to the Committee of Public Accounts and to the Deregulation Committee its evidence and any other documents relating to matters of common interest; and
- (d) to meet concurrently with any other such committee for the purposes of deliberating, taking evidence, or considering draft reports.

The following were nominated Members of the Committee on 14 July 1997:

Mr David Atkinson	Mr Nigel Jones
Mr Nigel Beard	Dr Ashok Kumar
Dr Michael Clark	Mrs Caroline Spelman
Mrs Claire Curtis-Thomas	Dr Desmond Turner
Dr Ian Gibson	Dr Alan W Williams
Dr Lynne Jones	

Dr Michael Clark was elected Chairman on 30 July 1997.

On 22 June 1998 Mrs Caroline Spelman was discharged and Mrs Jacqui Lait added to the Committee

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2. The Committee published its *Report on The Cloning of Animals from Adult Cells* on 20th March 1997.² The Government published its *Response to that Report* in December 1997.³

3. We welcomed the Government's *Response*, in particular its reaffirmation that the cloning of human individuals is "ethically unacceptable" and would not be permitted in the UK.⁴ However, the Government's *Response* did not allay all our concerns. Consequently we wrote to the Minister for Science in February 1998 seeking further clarification on:

- (i) the scope of the Human Fertilisation and Embology Act;
- (ii) the Government's intentions regarding public consultation on matters relating to cloning;
- (iii) progress on the development of an international agreement on bio-ethics and
- (iv) Government thinking on reaching the stage for considering the ethics of genetic modification for animals as distinct from that of humans.

4. Our letter of 19th February 1998 to the Minister and his reply, which was received on 15th July 1998, are appended to this Report.

¹ First Report from the Science and Technology Committee, Session 1995-96, on *The Cloning of Animals from Adult Cells*, HC 334, para 5.

² Fifth Report from the Science and Technology Committee, Session 1996-97, on *The Cloning of Animals from Adult Cells*, HC 334.

³ *Response to the Cloning of Animals from Adult Cells*, Government Response to the Fifth Report of the Select Committee on Science and Technology, 1997-98, Cm 3815.

⁴ Government Response, Cm 3815, para 2 and 14.

FOURTH REPORT

The Science and Technology Committee has agreed to the following Report:—

THE CLONING OF ANIMALS FROM ADULT CELLS

1. On 27th February 1997 our predecessor Committee, the Science and Technology Committee in the 1992-97 Parliament, undertook an inquiry into experiments at the Biotechnology and Biological Sciences Research Council-sponsored Roslin Institute, following an announcement, a few days earlier, that scientists at the Institute had succeeded in producing a living sheep by fusing nuclear DNA taken from a mammary cell of an adult sheep and an egg cell from which nuclear DNA had been removed. The points which concerned the Committee most were the scientific challenge of the work and the benefits which might be expected to flow from it; and the adequacy of the law regarding cloning and related issues in both humans and animals.¹

2. The Committee published its Report on *The Cloning of Animals from Adult Cells* on 20th March 1997.² The Government published its Response to that Report in December 1997.³

3. We welcomed the Government's Response, in particular its reaffirmation that the cloning of human individuals is "ethically unacceptable" and would not be permitted in the UK.⁴ However, the Government's Response did not allay all our concerns. Consequently we wrote to the Minister for Science in February 1998 seeking further clarification on:

- (i) the scope of the Human Fertilisation and Embryology Act;
- (ii) the Government's intentions regarding public consultation on matters relating to cloning;
- (iii) progress on the development of an international agreement on bio-ethics; and
- (iv) Government thinking on matching the regime for considering the ethics of genetic modifications for animals to that of humans.

4. Our letter of 5th February 1998 to the Minister and his reply, which was received on 15th July 1998, are appended to this Report.

¹ Fifth Report from the Science and Technology Committee, Session 1996-97, on *The Cloning of Animals from Adult Cells*, HC 373-I, para 4.

² Fifth Report from the Science and Technology Committee, Session 1996-97, on *The Cloning of Animals from Adult Cells*, HC 373-I.

³ *The Cloning of Animals from Adult Cells*, Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, 1996-97, Cm 3815.

⁴ Government Response, Cm 3815, paras 9 and 16.

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

TUESDAY 28 JULY 1998

Members present:

Dr Michael Clark, in the Chair

Mr Nigel Beard

Dr Ian Gibson

Dr Lynne Jones

Mr Nigel Jones

Dr Ashok Kumar

Dr Desmond Turner

Dr Alan W. Williams

The Committee deliberated.

Draft Report (The Cloning of Animals from Adult Cells), proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 4 read and agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the following Papers be appended to the Report:

Letter dated 5th February 1998 from the Chairman of the Committee to Mr John Battle MP, Minister for Science, Energy and Industry; and

Letter dated 14th July 1998 from Mr John Battle MP, Minister for Science, Energy and Industry to the Chairman of the Committee and a memorandum from the Office of Science and Technology. — (*The Chairman.*)

The Committee deliberated.

* * * * *

[Adjourned till Wednesday 29th July at a quarter to Four o'clock]

APPENDICES

Letter from the Chairman of the Committee to Mr John Battle MP, Minister for Science, Energy and Industry, Department of Trade and Industry

THE CLONING OF ANIMALS FROM ADULT CELLS

The Committee welcomed the publication of the Government's reply to its report on *The Cloning of Animals from Adult Cells* which was published last December. In particular, the Committee are pleased that the Government have reaffirmed its position that work which would result in the creation of experimental human beings should not be carried out.

However, the Committee remain of the opinion that there is room for improvement in the legislation regarding genetic manipulation—specifically regarding the scope of the Human Fertilisation and Embryology Act (paragraph 29 of our Report) and the banning of human cloning through primary legislation (paragraph 33 of our Report).

The Committee firmly believes, as we said in our Report, that anyone attempting cloning without the express consent of the Human Fertilisation and Embryology Authority should face criminal charges. The recent consultation paper released by the Human Genetics Advisory Commission, by saying "Anyone undertaking, without an HEFA licence, an activity governed by the . . . Act may be guilty of a criminal offence", seems to concur with our interpretation that this is not the case at present.

The Committee noted the Government's intention to give these matters careful consideration, and the Commission's consultation paper is to be welcomed as a part of that consideration. Nevertheless, the Committee remain convinced that there is a need for action both to allay public concerns and to strengthen the regulatory system. Given the potential for rapid developments in genetic science, we believe that there is also a need for a degree of urgency. It is in this light, therefore, that we are seeking further clarification of the Government's intentions and, in particular, an indication of the timetable you have in mind.

The Committee are also keen that the international nature of scientific study in the field is fully recognised and remain convinced that an international agreement on bioethics is a necessity (paragraph 16 of our Report). Therefore, the Committee would be grateful to know what progress has been made in this area, whether through the EU or the UN, and whether there is any likelihood of an agreement in the near future.

We were pleased that the Government agreed that the Human Genetics Advisory Commission and, where appropriate, the Human Fertilisation and Embryology Authority, should be consulted about animal experiments which appear to have major implications for the science of human genetics. We would be interested to learn how the Government plan to achieve this in practice. However, we do not consider that this meets our recommendation that the regime for considering the ethics of genetic modification in humans should be matched by an effective regime for animals; nor does the recent appointment of an ethicist to the Farm Animal Welfare Council (although this is a welcome development). The Committee would appreciate a more detailed indication of the Government's thinking on this matter than that provided in the reply to our Report.

The Committee noted that the Government would be considering responsibility for redundancy costs within the context of the Comprehensive Spending Review. We urge the Government to seek a way for departments funding research to manage their research contracts without imposing unnecessary costs on the science budget. Government departments should be encouraged to give us as much notice as possible of termination of research projects.

We would be grateful to receive a memorandum detailing the Government's intentions in these matters, although, should you consider it more appropriate, the Committee would consider covering these matters orally.

5 February 1998

Letter to the Chairman of the Committee from Mr John Battle, MP, Minister for Science, Energy and Industry, Department of Trade and Industry

I wrote to you on 17 February acknowledging your letter of 5 February concerning the Government's response to the Science and Technology Committee's report "The Cloning of Animals from Adult Cells". In that letter, I confirmed that I would be preparing a memorandum addressing the additional points made by the Committee.

I apologise for the delay in completing the memorandum. This was partly due to the broad interest over a number of departments, and partly due to recent developments which needed to be incorporated in what we assumed was the final draft.

I hope that the Memorandum assures the Committee that the Government takes this issue very seriously and is keen to ensure that it is handled effectively.

14 July 1998

Memorandum submitted by the Office of Science and Technology

THE CLONING OF ANIMALS FROM ADULT CELLS

INTRODUCTION

1. In February 1997, the news that a sheep (Dolly) had been cloned from an adult cell generated considerable interest both nationally and internationally. Hailed as a remarkable scientific breakthrough, the news triggered much discussion on the ethics of cloning. The House of Commons Science and Technology Select Committee decided to hold an Inquiry into this work and reported to the House on 18 March 1997¹. The Government published its Response in December 1997².

2. On 5 February 1998, the Committee requested further information on the following points: (i) greater clarification on the legal situation; (ii) a progress report on international developments, in particular an agreement on bioethics; and (iii) Government thinking on matching the regime for considering the ethics of genetic modifications in animals to that for humans. This Memorandum addresses these points. It does, however, need to be borne in mind that this is a rapidly evolving area, and a number of activities are currently underway that will have a bearing on future policy. A public consultation exercise on the biosciences is planned to commence later in the year. This will also be advice from the Human Genetics Advisory Commission (HGAC) and Human Fertilisation and Embryology Authority (HFEA) following their consultation exercise on cloning.

PUBLIC CONSULTATION ABOUT DEVELOPMENTS IN BIOSCIENCES

3. It is widely acknowledged in the field of biosciences that genetic research has the potential for substantial growth over the next few years. It has already made a big contribution to healthcare, from development of antibiotics and vaccines to human insulin and cholesterol test kits. By 2000, it is claimed that all new pharmaceutical products launched will include some input from the bioscientific field. Bioscience also has a global dimension. Its development and industrial exploitation is world wide and the questions it gives rise to are of international concern. These wider issues continue to be addressed by the international community (cf paragraphs 15-17 below). As stated in its Response³, the Government said that it would "also strive to ensure that the debate on the ethical issues surrounding biosciences keeps pace with advances in these technologies".

4. As reported in the Government Response⁴, the Human Genetics Advisory Commission (HGAC) and the Human Fertilisation and Embryology Authority (HFEA) jointly convened a working group to explore ways of holding a consultation exercise on cloning. They issued a consultation document "Cloning Issues in Reproduction, Science and Medicine" in January this year. The document highlights the various ethical issues raised by identifying the different potential uses of cloning technologies and is primarily addressed to specialists in organisations with scientific, legal, clinical or ethical interests. These, and members of the public who have requested copies were asked to submit their responses to the document by 30 April 1998. The HGAC and HFEA are considering the responses before advising Ministers later this year.

5. Much commentary and speculation on biosciences, and cloning in particular, has originated from a number of pressure groups and scientists from various disciplines. whilst this has increased awareness of cloning as a science, it has also led to some anxiety. The Government is sensitive to these concerns and recognises the need to maintain public confidence. In order to ensure that any steps taken to allay public concerns, discuss difficult ethical questions, and, if it is deemed necessary, strengthen the regulatory system are well informed and correctly focused, the Government in November 1997 announced a public consultation exercise to discuss the wider issues raised by developments in the biosciences as a whole. An important goal for the consultation exercise will be to engage the public in this important debate. In particular, the Government is keen to identify what interests and concerns the public most, and why. The results will help assess the adequacy of the current regulatory and advisory systems and provide invaluable information to policy makers.

¹ "The Cloning of Animals from Adult Cells", House of Commons Science and Technology Committee, Session 1996-97, Fifth Report (printed 18 March 1997), Vol. 1.

² "The Cloning of Animals from Adult Cells", Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, Session 1996-97 (Cm 3815).

³ "The Cloning of Animals from Adult Cells", Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, Session 1996-97, Cm 3815, page 7, paragraph 27.

⁴ "The Cloning of Animals from Adult Cells" Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, Session 1996-97, Cm 3815, page 4, paragraph 14.

6. The first stage of this consultation exercise was a meeting in March 1998 between the Minister for Science, Energy and Industry and representatives of organisations experienced in science communication and public consultation to discuss the scope of the consultation and the process. Discussions focused on how experience has shown that it is crucial to develop science communication beyond the merely reactive, so that Government, for example, is not always perceived as trying to simply respond to the latest story of scare, but seen to be developing a better understanding and appreciation of science, its role, benefits and limitations. There was a widespread feeling that there was a need for the public to make the running as far as possible and then seek to answer questions raised, rather than simply provide information to the public. Another factor was that any public activity needs careful planning and it is important to do it well rather than simply do it quickly.

7. Following on from this meeting, a broadly based steering group has been set up to assist with taking forward the public debate, under the chairmanship of OST. They will advise the Government on the management of consultation. The next stage will be to set up activities which will allow public views to be accessed. This will start during the summer.

THE LAW RELATING TO THE CLONING OF HUMANS

8. As the Government made clear in its Reponse to the Fifth Report of the House of Commons Select Committee on Science and Technology, "cloning of human individuals cannot take place in this country"⁵. The Human Fertilisation and Embryology Act 1990 expressly prohibits nuclear replacement in a cell of an embryo. Other forms of cloning involving embryo splitting or nuclear replacement in eggs cannot take place because the HFEA has made clear its decision that it will not license any treatment involving such techniques or any research to develop cloning for such treatment purposes.

9. The Committee commented on the wording used in the joint HGAC/HFEA consultation document to describe the legal position covering cloning. Section 41 of the 1990 Act is quite clear. It provides that any person who contravenes section 3(3) of the Act (cloning by nuclear replacement in the cell of an embryo) or section 3(1) of the Act (bringing about the creation of an embryo etc without a licence) is guilty of an offence, punishable by imprisonment, a fine or both.

10. The Government reaffirms that it will keep the situation under review. However, decisions about the desirability of any further legislative control of cloning are not envisaged at least until the HGAC/HFEA have considered the results of their consultation and advised Ministers.

ETHICS IN RESPECT OF ANIMALS

11. On 1 April Home Office Ministers announced that additional animal welfare experts would be appointed to the Animal Procedures Committee (APC). These include Dr Maggy Jennings of the RSPCA's laboratory animal division and Dr Gill Lanley of the Dr Hadwen Trust for Humane Research. Dr Langley is also a scientific adviser to the British Union for the Abolition of Vivisection. Dr Jennings and Dr Langley bring to the Committee expertise relating to animal welfare and to the development and use of alternatives which replace animal use, reduce the number of animals used in any given project and refine procedures to minimise suffering (the three Rs). Additionally, the new Chairman of the APC, the Rev Professor Michael Banner, Professor of Moral and Social Theology at Kings College, London, also chaired the Committee to consider the Ethical Implications of Emerging Technologies in the breeding of Farm Animals. The APC and the Farm Animal Welfare Council now hold regular liaison meetings involving the Chairman and members of these two bodies.

12. In respect of the ethical concerns in relation to the genetic modification of animals, there have been developments in respect of the Animal (Scientific Procedures) Act 1986. Applications which raise sensitive issues are now referred upwards to senior staff in the Home Office Inspectorate and to the relevant policy unit. Also, new proposals to develop or improve techniques which might have implications for human genetics have been added to the upward referral policy, which could lead to the Government seeking advice from the HGAC/HFEA as appropriate.

13. Home Office Ministers have also announced that all establishments designated under the terms of the A(SP) Act must have local "ethical review processes" in place by 1 April 1999. These processes have recently been the subject of consultation and subsequent revised guidance was issued to all establishments in April this year. This guidance sets out the aims of the ethical review process and includes:

- providing independent ethical advice to the Certificate holder, particularly with respect to project licence applications and standards of animal care and welfare; and
- promoting the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible applications of the 3Rs.

⁵ "The Cloning of Animals from Adult Cells" Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, Session 1996-97, Cm 3815, page 4, paragraph 16.

CONSIDERATION OF ETHICS IN RESPECT OF BOTH HUMANS AND ANIMALS

14. There continues to be inter-departmental consideration of how the wider issues (both ethical and social) raised by developments in biotechnology should be addressed. The United Kingdom already has in place an extensive, world leading, network of advisory bodies considering biotechnology and genetics—for example the HGAC, the Advisory Committee on Genetic Testing (ACGT), Gene Therapy Advisory Committee (GTAC)—all of which consider particular “human” ethical issues. In light of the recent calls to overhaul the scrutiny of animal experiments, the Government has been looking at the possibility of matching the regime for considering the ethics of genetic modification in humans with that for animals. Alongside the recommendation of the 1994 Banner Committee to create an advisory committee with responsibility for broad ethical questions relating to developments in the use of animals⁶, there have also been representations on the possibility of establishing a National Bioethics Committee similar to those found in a number of other countries. However, before embarking on any further consideration on this issue, the Government wishes to explore public views on the effectiveness of the present structure and specific views on how, if at all, the current system might be improved.

INTERNATIONAL DEVELOPMENTS SINCE PUBLICATION OF GOVERNMENT RESPONSE

15. At the international level the Government has been pleased with the progress made in developing international agreements to prohibit human reproductive cloning over recent months. The United Kingdom has been closely involved in a number of initiatives which call for the reproductive cloning of human beings to be banned:

- EC Biotechnology Patents Directive⁷ which forbids the issue of a patent on work leading to intentional cloning of human beings.
- A protocol forbidding the cloning of human beings has been developed under the Council of Europe Convention on Human Rights and Biomedicine⁸.
- A UNESCO Declaration on the Human Genome and Human Rights, unanimously adopted on 11 November 1997⁹, of which Article 11 states that “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted”.

16. At the advisory level, the European Commission had been able to call on the advice of the “Group of Advisers on the Ethical Implications of Biotechnology” (GAEIB) until their mandate expired in December 1997. They were instrumental in calling for the European Commission to express clear condemnation of human reproductive cloning in the legal texts concerning the Fifth Framework RTD Programme (1998–2002) and the Directive on the legal protection of biotechnological inventions. The legal text of the Fifth Framework Programme, adopted at the Research Council meeting of 12 February 1998 makes the following comment:

“No research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such alteration heritable will be carried out under the present Framework programme. In the same way, no research activity, understood by the term “cloning” will be conducted with the aim of replacing a germ of embryo cell nucleus with that of the cell of the individual, from an embryo or coming from a later stage of development to the human embryo”.

17. Given the increasing need to further address ethical questions arising—amongst others—from modern biotechnology, the Commission expanded GAEIB to form the “European Group of Ethics in Science and New Technologies” which met for the first time on 19 February 1998. The new Group is composed of 12 experts and its remit has been enlarged to cover all new technologies as well as scientific research.

REDUNDANCY COSTS IN CONTEXT OF COMPREHENSIVE SPENDING REVIEW

18. The Committee also asked for additional information about redundancy costs in the context of the Comprehensive Spending Review. The Government agrees that Government Departments should give contractors as much notice as possible of the termination of research projects, and set out its policy on such matters in more detail in its Response to the Committee’s report “The Research Council System: Issues for the Future”¹⁰.

⁶ Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals 1995—paragraph 3.34, page 18.

⁷ European Parliament and Council Directive on the legal protection of biotechnological inventions COM(97) 446 final.

⁸ Council of Europe (1997), Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Strasbourg: Council of Europe 1997.

⁹ “Universal Declaration on the Human Genome and Human Rights”, published by UNESCO, November 1997.


¹⁰ House of Commons Science and Technology Committee, Session 1997–98 First Special Report—The Government’s Response to the Science and Technology Committee’s Fourth Report, Session 1996–97, The Research Council System: Issues for the Future, HMSO HC302, November 1997.

CONCLUSION

19. The Government is committed to ensuring that the public debate on the ethical issues surrounding biosciences keeps pace with the ever increasing developments in this area of science. A major milestone to be achieved will be this year's public consultation exercise which will involve industry, advisory bodies, interested groups and members of the general public. In the light of this exercise, the Government will consider what, if any, action is required.

14 July 1998

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