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 Session / Department of Trade and Industry, Office of Science and Technology.

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OFFICE OF SCIENCE AND TECHNOLOGY

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GOVERNMENT RESPONSE TO THE FIFTH REPORT OF THE HOUSE OF COMMONS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY 1996-97 SESSION

INTRODUCTION

1. The Government welcomes the careful consideration and the speed with which the Select Committee addressed this issue. The Government, along with the Committee, recognises the growing importance of genetics and genetic techniques and the speed with which developments are taking place. Research in the fields of genetics and biotechnology is fast moving at home and abroad. The UK can take pride in being a world leader in these areas of research.

2. The announcement on the 23 February 1997 that scientists at the Biotechnology and Biological Sciences Research Council (BBSRC) sponsored Roslin Institute had achieved a breakthrough in cloning "Dolly" from adult sheep cells heralded an important scientific achievement albeit with ethical implications. This major technical advance might in time lead to significant new benefits to research in human and animal health, such as new sources of production of important pharmaceutical products in animals' milk, and opportunities for treatment of mitochondrial disorders, infertility, cancers and other inherited diseases. This achievement was one of many in a long series of advances, providing further evidence of the United Kingdom's strength in this area.

3. The Committee reaffirmed its desire for a ban on the deliberate cloning of human beings. The Government has since reaffirmed its policy that the deliberate cloning of human individuals is ethically unacceptable, though it is not opposed in principle to the use of cloning techniques where research is being carried out on serious inherited illnesses, and where the end result will not involve cloning of human individuals.

4. As the Committee recognises, many countries and international bodies are presently examining how human reproductive cloning should be regulated. The Government recognises the potential advantages of suitable international agreements in the area of human reproductive cloning and actively participates in discussions that may lead to such agreements. However, during these discussions, the Government confirms its position, outlined in paragraph 3 above.

5. The Government fully understands the Committee's concerns associated with developments in this field and endorses the need to maintain public confidence. The Committee highlighted some of the ethical issues arising from cloning, and in doing so, has helped the Government to ensure that these topics

have been aired in a measured way. The Committee particularly highlights the need to examine existing legislation to ensure that it is sufficient to prevent human reproductive cloning through the technique developed at the Roslin Institute.

6. The United Kingdom has a number of independent mechanisms for addressing ethical, legal and technical issues relating to genetic research in both humans and animals. The Human Genetics Advisory Commission (HGAC) takes a broad overview of developments in human genetics and reports on the broad social, ethical and economic issues arising from these developments. The Human Fertilisation and Embryology Authority (HFEA) also acts as a safeguard for public concerns by overseeing and applying the provisions of the 1990 Human Fertilisation and Embryology (HFE) Act.

7. The Government's role is to foster excellence in United Kingdom genetics research. It also needs to ensure that public confidence is maintained. The Office of Science and Technology (OST) plays an important role. OST seeks to ensure that departmental S&T policies in this area are co-ordinated, with the aim of more effective collaboration. The recent OST guidelines "The Use of Scientific Advice in Policy Making" set out best practice for the use of science, including genetics, by policy makers. OST also directly supports the work of the HGAC, encouraging it in its commitment to communicate and consult more widely on issues of public concern.

8. The Government's comments on the Select Committee's report are set out below. This Response follows broadly the structure of the Committee's report – the numbers in brackets refer to the relevant paragraph number of the Committee's report.

THE SCIENTIFIC CHALLENGE AND THE BENEFITS OF THE RESEARCH

9. The Government agrees with the Committee's conclusion (12) that work which would create experimental human beings should not be carried out. The Minister for Public Health made the Government's position clear: "We regard the deliberate cloning of human individuals as ethically unacceptable. Under United Kingdom law, cloning of individual humans cannot take place whatever the origin of the material and whatever technique is used. Research into some serious inherited illnesses in humans, such as some forms of encephalomyopathy, cardiovascular disease and type II diabetes, can take place using cloning techniques. However, where such research involves the use of human embryos it is strictly controlled under the terms of the Human Fertilisation and Embryology Act 1990 which would require a licence to be issued by the Human Fertilisation and Embryology Authority[1]".

1 House of Commons Official Report, Parliamentary Debates (Hansard) Thursday 26 June 1997, Written Answers Column 615.

International

10. The Government notes the Committee's view (13) that given the international nature of science, regulation of such technologies cannot be confined to the national level. The Government also sees potential advantages in reaching an international agreement on the control of human reproductive cloning (16). Many national/international bodies and countries are presently examining the regulation of human reproductive cloning and the Government will consider carefully any international proposals which are put forward. But the issue of human reproductive cloning is not straightforward. The Government accepts that research into some serious diseases can take place using cloning techniques. However, the deliberate cloning of human individuals is morally unacceptable. This echoes the Committee's comment that research "should relieve suffering and improve the health of individuals and the well being of human-kind as a whole"[2].

Regulation in the United Kingdom

11. The Government notes the Committee's conclusion that a well developed system for considering the ethical implications of developments in human genetics already exists in the United Kingdom. (18).

12. The Human Fertilisation and Embryology Authority (HFEA) is a non-departmental public body, which was established in 1991 by the Human Fertilisation and Embryology Act (HFE Act) 1990. Its principal task is to license and monitor those clinics that carry out in-vitro fertilisation, donor insemination and embryo research and to regulate the storage of gametes (eggs or sperm) and embryos. The Secretary of State for Health is accountable for the HFEA to Parliament.

13. The HFE Act 1990 provides limitations on the types of research conducted involving human embryos. Section 3(1) of the Human Fertilisation and Embryology Act 1990 provides that research licences may be issued by the HFEA where appropriate to authorise the creation of embryos in vitro and the keeping or use of embryos (up to the appearance of the 'primitive streak'/maximum period of 14 days), but only for the purposes of the research project specified in the licence. When considering an application for a research licence the HFEA will authorise only that research which is considered ethically acceptable within the framework of the 1990 Act, and which has received the prior approval of a properly constituted ethics committee.

2 House of Commons Science and Technology Committee, Session 1996-97, Fifth Report (printed 18 March 1997), Vol. I, Page viii, paragraph 14.

14. The Government recognises the acute public sensitivities there are about developments in human genetics. The Human Genetics Advisory Commission (HGAC) was established in 1996 to keep under review scientific progress at the frontiers of human genetics, report on issues arising from developments expected to have wider social, ethical, and/or economic consequences (e.g. in relation to insurance, patents, employment and public health) and to advise on ways to build public confidence in, and understanding of, the new genetics. It is currently exploring together with the HFEA, ways of holding a consultation exercise on cloning. A joint working group has been set up to take this forward.

15. The Government agrees with the Committee's statement that animal experiments similarly fall under a number of controls (19). The Genetically Modified Organisms (Contained Use) Regulations 1992 (as amended) control all activities in containment involving organisms whose genetic material has been altered using a non-natural technique. Not all nuclear transfer activities will necessarily result in genetic modification as defined in the Regulations. However, where it does, for instance when nuclear transfer is used to produce a transgenic animal containing "foreign" DNA, the facility where the animals are bred and kept will have to be notified to the Health and Safety Executive (HSE). HSE are advised by the Health and Safety Commission Advisory Committee on Genetic Modification (ACGM). In some cases, individual contained use activities involving genetically modified organisms (GMOs) must also be notified to HSE.

The Law Relating to the Cloning of Humans and Embryo Research

16. The Government notes the Committee's recommendation that Parliament should reaffirm a ban on human reproductive cloning (33). The Government recently made its position clear – basically, the cloning of human individuals cannot take place in this country (cf. paragraph 9 above).

17. The Government will consider carefully, in the light of developments, whether the legislation needs to be strengthened in any more specific way. When doing so, it would take into account the views of Members of Parliament, the HGAC, HFEA and the responses to any more general consultation on the broader issues.

Regulation of Animal Experiments

18. The Government agrees with the Committee that research using animals in the United Kingdom is only permitted if licensed under the Animals (Scientific Procedures) Act 1986 (34). This Act is administered by the Home Office. The Animal Procedures Committee advises the Home Secretary on matters relating to the Act and his functions under it. It also considers ethical arguments when deciding what advice to give the Home Secretary. However, this Committee does not see the vast majority of licence applications.

19. The Government agrees with the Committee that the current practice, on the regulation of animal experiments, is basically sound (36). The Government also agrees with the Committee that there is no need for explicit regulation of experiments involving only "harvested" material, on the understanding that this material has been collected from an animal after it has been humanely killed. Work on material harvested from animals can often be done without the need for specific authorities under the Animals (Scientific Procedures) Act 1986. In the case of the Roslin cloning work, such authorities were only required to validate new advances in genetic research already made in the laboratory using harvested tissue for which no authority under the 1986 Act had been required.

20. The Government notes the Committee's recommendation that the regime for considering the ethics of genetic modification in humans should be matched by an effective regime for animals (37). At present, there is no central Government committee with a specific remit for providing ethical advice on all aspects of the use of animals in scientific procedures. However, as well as the Animal Procedures Committee, there is also the Farm Animal Welfare Council, – which provides independent advice to Agriculture Ministers. This Council has been asked to advise on whether the application of the cloning technique is likely to have any implications for farm animal welfare. An ethicist has recently been appointed to membership of the Council so that it can take account of ethical considerations in formulating its advice.

21. The Government agrees with the Committee that the HGAC and, where appropriate, the HFEA, should be consulted about animal experiments which appear to have major implications for the science of human genetics (38).

MAFF FUNDING OF THE EXPERIMENTS

22. MAFF has followed the approach in the 1993 White Paper *Realising Our Potential*, which concluded that "the 'Rothschild' principle remains as valid today as twenty years ago" and "that the utility and quality of research needed by civil Government Departments are best guaranteed by leaving them free to determine their own needs and commission the work from suppliers who compete to meet their specifications." The Government acknowledges the importance of the Roslin and other BBSRC institutes to the Science Base and British industry and recognises their role in the public sector, as confirmed by the outcome of the 1996/97 Prior Options review. MAFF is a customer for research in support of its policy aims. It funds research at BBSRC and NERC institutes, universities and its own Agencies, as well as with many other contractors. MAFF prioritises its research programme regularly and seeks to fund work which is most necessary to support these policy aims, and which provides it with best value for money.

23. MAFF funding is not provided as grant-in-aid but is allocated to specific projects through contracts, mostly of three year duration, with set end-dates. This allows the Department flexibility in managing its research programme. It also makes it possible to place work competitively and to draw on the full breadth of the science base, particularly the universities and institutes.

24. MAFF's financial relationship with BBSRC institutes is governed by identical "umbrella" contracts negotiated by BBSRC on behalf of the institutes and signed in early 1996. These contracts commit MAFF to paying the agreed costs for each project, but exclude liability for redundancy costs. Accordingly, acting on the basis of the customer/contractor principle, as endorsed by the 1993 White Paper, MAFF has not thought it appropriate to fund the cost of redundancies. It is the responsibility of each institute to plan its research programmes and staff resources against agreed contracts. The contracts provide for MAFF to furnish advance information which is intended to allow institutes and BBSRC time to plan for change and if necessary make appropriate arrangements for redundancies.

25. The use of contracts does not restrict MAFF's ability to plan a strategic research programme. This is shown by the pivotal role MAFF has played, as the major funder of research into cloning technologies at Roslin supporting it to its current level of success and building on BBSRC funded basic science. MAFF has committed more than £2million to this area of research since 1991. Since the publication of the Committee's report, MAFF has funded a further project with Dr Wilmut up to March 1999. BBSRC has invited a research proposal for additional funding from Dr Wilmut and this is currently subject to normal peer review procedures. A number of other research projects, many involving collaboration with industry and other funders, are also under discussion. MAFF payments to Roslin for research contracts in the current financial year are now expected to be about £500k lower than in 1996/97, at around £4 million.

26. The Government accepts that changing policies and research requirements in MAFF have led to significant changes in funding at BBSRC sponsored institutes. These have resulted in substantial redundancy costs amounting to £600k at Roslin this year, which have been borne by BBSRC and Science Budget. The Government plans to examine the responsibility for redundancy costs in the context of the Comprehensive Spending Reviews.

CONCLUSION

27. The Government fully recognises that the strength of the United Kingdom's science base made possible the breakthrough at Roslin. The cloning of Dolly from adult sheep cells aroused substantial public interest and concern. The Government must maintain public confidence in the future handling of such cases. The work of the HFEA and HGAC will go a long way to ensure that public

debate is focused on the appropriate areas. Meanwhile the Government will continue to foster excellence in UK genetics research as it has exciting potential to bring about benefits in areas such as health and agriculture, and thus improve the quality of our lives. The Government will also strive to ensure that the debate on the ethical issues surrounding biosciences keeps pace with advances in these technologies.

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