



**ANIMALS AND BIOTECHNOLOGY**  
A REPORT BY THE AEBC

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• **A • E • B • C** •

AGRICULTURE AND ENVIRONMENT  
BIOTECHNOLOGY COMMISSION



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## **EXECUTIVE SUMMARY**

Developments in biotechnology have huge implications for society's relationships with animals. It is vital that we think about the issues now, not when GM or cloned animals are reaching our farms or are ready for release into the environment.

Government and the livestock industry must get it right, to avoid the problems we have seen with public acceptance of the introduction of GM crops and food. The use of genetic biotechnology is particularly sensitive because of the speed and nature of the changes to animals it makes possible. There is a broad range of views about these changes. Some people see them as an extension of previous selective breeding. Some are already worried about the potential for making previously impossible changes. Some are against them in principle. Therefore the methods for giving independent advice to Government and engaging the public on these new developments must be strengthened.

Commercial applications of GM or cloning to farm animals in the UK, with the exception of GM sheep that produce pharmaceuticals in their milk, are unlikely in the next few years. So the UK has time to plan for these potential developments. And planning is needed: in other countries prize cows and bulls have already been cloned and sold, and research on farm animals is developing.

We have taken a strategic look at the issues and investigated the regulatory system to see if it could cope with future developments in GM and cloned animals. In doing so we made sure that our recommendations were influenced by the public's views. Our research shows that mistrust of official institutions affects attitudes to these issues. There seems to be little outright rejection of applying GM and cloning to animals, but people are worried about the speed of developments and the possibility of mistakes. They are anxious about the possibility of substantially altering the nature of animals, and want to understand the purposes and justification for applying genetic biotechnology. Above all they ask for a transparent regulatory system that they can trust.

We therefore believe there is a strong case for a new advisory body to take a strategic look at these issues, particularly in relation to farm animals. It makes sense for it to do so in the context of the application of GM and cloning to other animals. Some developments like cloning are beginning to be applied to farm animals, pets and research animals. The new body would also need to examine genetic biotechnology in agriculture in the context of current and future developments in livestock farming and consumer attitudes.

### **RECOMMENDATION**

**A NEW STRATEGIC ADVISORY BODY SHOULD BE SET UP BY STATUTE TO EXAMINE ISSUES RAISED BY THE USE OF GENETIC BIOTECHNOLOGY ON FARM ANIMALS IN THE CONTEXT OF ITS USE ON OTHER ANIMALS AND CURRENT LIVESTOCK FARMING PRACTICES.**

Decision-makers should engage the public far more effectively on which applications of GM, cloning or more conventional technology are acceptable. Adequate funds will be needed for this.

**RECOMMENDATION**

NEW METHODS AND FUNDING SHOULD BE USED TO ENGAGE THE PUBLIC IN DECISIONS ABOUT GENETIC BIOTECHNOLOGY.

GM and cloned animals should be part of the same regulatory system as other animals wherever possible. All developments in livestock farming need to be justifiable. They need to have a clear purpose and be seen in the context of society's wider relationship with animals, whether they involve traditional or new techniques. We think, however, that because of public concerns, there should be a strong focus on the use of GM and cloning.

The existing law relating to farm animals meets most concerns about the welfare of future GM farm animals and particularly any problems which could cause risks to human health or the environment. We believe, however, that the law as it stands would not necessarily protect animals from some potential fundamentally objectionable changes to their natures. We also think that the existing legislation on animal welfare needs to be updated and consolidated. It is good news that DEFRA is now reviewing it. The effectiveness of the interpretation and enforcement of existing regulation relating to farm animals should be independently scrutinised. Effective enforcement is needed both to improve animal welfare and increase public trust in the regulatory system.

**RECOMMENDATION**

GM, CLONED AND CONVENTIONAL ANIMALS SHOULD BE GOVERNED BY THE SAME REGULATIONS WHEREVER POSSIBLE. THE 1911 PROTECTION OF ANIMALS ACT SHOULD BE UPDATED AND OTHER PIECEMEAL ANIMAL WELFARE LEGISLATION CONSOLIDATED. PROVISION WILL BE NEEDED TO PROTECT FARM ANIMALS FROM DEVELOPMENTS WHICH SUBSTANTIALLY ALTER THEIR NATURE IN UNACCEPTABLE WAYS. THE EFFECTIVENESS OF THE INTERPRETATION AND ENFORCEMENT OF EXISTING FARM ANIMAL WELFARE REGULATIONS SHOULD BE REVIEWED.

There is also a need for adequate monitoring of cloned and GM farm animals, if and when they enter conventional production, because there are fears of unanticipated health or welfare problems in adult animals.

**RECOMMENDATION**

POST-COMMERCIALISATION MONITORING OF GM AND CLONED FARM ANIMALS SHOULD BE PLANNED TO LOOK FOR UNEXPECTED WELFARE OR HEALTH PROBLEMS.

Thought should also be given ahead of time to people's attitudes to purchasing or consuming products from GM or cloned animals. Labelling and segregation in production will be needed to guarantee consumer choice if GM or cloned animals enter commercial production.

**RECOMMENDATION**

ARRANGEMENTS SHOULD BE MADE TO MAINTAIN CONSUMER CHOICE ABOUT WHETHER TO PURCHASE MEAT OR OTHER PRODUCTS FROM GM AND CLONED ANIMALS.

Unlike GM and cloned farm animals, the commercialisation of GM fish raises significant environmental concerns because of the possibility of the fish escaping from the aquatic net

pens used in offshore fish farms. Therefore, while there is significant uncertainty about the environmental consequences of the escape of GM fish into the wild and about the containment of the fish, we believe that GM fish should not be raised in offshore aquatic net pens. This judgement could change if the containment was assessed as adequate by the regulatory authorities or the environmental assessment changed. The release of GM insects into the environment must also be considered very carefully.

### **RECOMMENDATION**

THE COMMERCIAL PRODUCTION OF GM FISH IN OFFSHORE AQUATIC NET PENS SHOULD NOT BE PERMITTED WHILE THERE IS SIGNIFICANT UNCERTAINTY ABOUT THE ENVIRONMENTAL CONSEQUENCES OF THE FISH ESCAPING TO THE WILD AND ABOUT THE CONTAINMENT OF THE FISH IN NET PENS.

To protect the environment and guarantee post-commercialisation monitoring of GM and cloned animals, a system for tracing the international import and export of these animals, and of GM eggs, semen and embryos and cloned reproductive material, should be developed. A sophisticated system is needed because a GM animal often looks no different to a conventional animal. As with all other issues in this area of development, the problem needs to be addressed before there is widespread concern or any problem arises.

### **RECOMMENDATION**

THE INTERNATIONAL MOVEMENT OF GM AND CLONED ANIMALS AND REPRODUCTIVE MATERIAL SHOULD BE MONITORED.

An aerial, grayscale photograph of a rural landscape. The terrain is characterized by rolling hills and a patchwork of fields, some of which appear to be planted in crops. The perspective is from a high vantage point, looking down and across the valley. The overall tone is muted and professional.

**PART 1**  
**THE CONTEXT**

## **PART 1.1**

### **OUR PURPOSE**

- 1 Our purpose was to take a strategic look at the current regulatory system in the light of present and future applications of biotechnology to animals in agriculture and the environment.
- 2 We have necessarily ranged more widely than our terms of reference, although our recommendations are focussed on agriculture and the environment. We have taken a broad view because, first, the regulatory system is complex. Some of the legislation is specific to GM animals, some to farm animals, and some applies to GM, cloned and conventional animals. Second, the technology is being applied to different kinds of animals, and issues arising in one area can affect public attitudes to developments in other areas. Third, it is important to consider biotechnology in the context of current conventional practices to animals, to avoid inconsistency.

## **PART 1.2**

### **OUR METHOD**

- 3 We have attempted an effective and innovative approach which gave appropriate weight to all relevant considerations. We first undertook a broad survey of applications of biotechnology to animals.
- 4 We then sought information about public attitudes and values. The AEBC has a remit to advise on the public acceptability of developments in agricultural and environmental biotechnology. We have been clear from the outset that public views must inform our recommendations about the regulatory system. Early in our work, therefore, we commissioned a literature survey, from Professor Glynnis Breakwell of Surrey University, of existing social research on attitudes to animals and biotechnology in the UK.
- 5 Professor Breakwell found that existing research consisted predominantly of quantitative opinion surveys, which gave some general indications of public attitudes in this area. Professor Breakwell noted that ‘overall there would seem to be little research on this topic area in the UK - indeed it appears that the issue of animals and biotechnology has not formed the sole focus of any research. Rather the issue has been addressed within research that has a different, or broader, focus such as biotechnology in general or animal welfare.’<sup>1</sup>
- 6 Consequently we decided to commission qualitative research on contemporary UK public attitudes and sensibilities towards animals with a view to understanding their subtleties and complexities.<sup>2</sup> We wanted, through qualitative social research, to explore in greater depth the subtleties of the different perspectives people have on animals and in particular about

<sup>1</sup> Breakwell G. *Research in the UK on public attitudes to biotechnology with animals*. March 2001.

<sup>2</sup> Macnaghten P. *Animal Futures: Public Attitudes and Sensibilities towards Animals and Biotechnology in Contemporary Britain*. October 2001.

applying GM and cloning to animals; and the nature of public expectations of the regulatory system. We are very grateful to those members of the public who participated in this study. We attach, at annexes B and C respectively, summaries of Professor Breakwell's literature review and Dr Macnaghten's report and have published both reports in full on our website.<sup>3</sup>

- 7 We reviewed the present legislation relating to GM and cloned animals in agriculture and the environment; and surveyed the various regulatory and advisory bodies<sup>4</sup> in order to identify any regulatory gaps in relation to the application of GM and cloning to animals. We did not make a detailed examination of the interpretation and implementation of regulation, but have made some observations on where we think further work might usefully be done on this. We bore in mind the Better Regulation Task Force's principles of better regulation in making recommendations.<sup>5</sup>
- 8 We consulted stakeholders openly about our emerging conclusions. We also recruited a public reference group with which to test out our thinking as it developed. We wanted to gain an idea of how our specific recommendations might be viewed by the public. The feedback we received from the reference group was important to the development of our report.<sup>6</sup> We are very grateful to members of the group and would commend the use of a similar reference group to others.

## PART 1.3 APPLICATIONS OF GENETIC BIOTECHNOLOGY TO ANIMALS

### GENETIC BIOTECHNOLOGY

- 9 In this section we outline some of the main areas where GM and cloning is either being applied to animals or looks likely to be applied in the future. We should stress that the following list is descriptive. It implies no approval or disapproval of any of the biotechnology applications, or of the claims or counter-claims made in relation to them or to what might be possible in the future. We consider in more detail the issues raised by some of the particular examples, and some of the general features of the technology, in Part 1.5 of this report. We define our use of the term genetic biotechnology in the glossary at Annex F.
- 10 **Conventionally**, pets and farm animals have all been selectively bred for particular characteristics perceived as desirable. The natural genetic variation in animal populations makes this possible. Selective breeding has produced all the many breeds of domestic dog. It has produced the modern dairy cow, pig and chicken which have been bred over many generations to be more productive than their ancestors. Selective breeding continues, aided now by artificial insemination techniques, which can mean an individual male with desirable

<sup>3</sup> [www.aebc.gov.uk](http://www.aebc.gov.uk)

<sup>4</sup> A description of the regulatory framework is at Annex A.

<sup>5</sup> See Part 2.1.

<sup>6</sup> See Annex D for executive summary of the final MORI report on the reference group.

characteristics can have a vastly greater number of offspring than was possible in the past. Improved statistical analysis has greatly increased the efficiency of conventional selective breeding. Marker-assisted breeding, which uses knowledge of farm animals' genetic maps to test animals for desired traits, is having a similar effect.

- 11 **Genetic biotechnology** potentially allows similar effects to conventional breeding to be achieved faster and with greater precision. Unlike conventional breeding, it can also be used to transfer genetic material from one species to another. It has also made possible the cloning of some individual adult animals which is impossible to achieve by conventional means. Compared with conventional technologies, genetic biotechnology also aims for a wider range of potential applications to animals, particularly for medical purposes.
- 12 The genetic modification and cloning of animals is not straightforward, however, especially for farm animal species. There are substantial welfare concerns relating to the production of transgenic founder animals. Most GM mammals are produced by injecting foreign DNA into fertilised eggs which are then implanted into 'foster' mothers. Cloning by cell nuclear transfer (which is the technique meant by 'cloning' in this report) involves transferring the nucleus from an animal cell into an egg cell which has had its nucleus removed. If this egg cell can be stimulated by electrical pulse to divide and to form an embryo, it can be implanted in a foster mother. Cloning can also be used to produce a GM mammal, by genetically modifying the animal cell before its nucleus is transferred. Some of the procedures associated with these techniques, such as the use of Caesarean section and other surgery, have welfare implications. The success rates of the techniques are low: for farm animals, overall, only about 10% of embryos on which genetic modification is attempted survive to birth and only about 10% of the offspring will be transgenic. So the overall rate of transgenic animal per injected embryo is 1% (compared to 3% in mice).<sup>7</sup> Cloning is similarly inefficient with success rates of 1-3%. A high proportion of clones result in late abortions or still borns, or have difficult births and post-natal abnormalities.<sup>8</sup> Also, as with the genetic modification of plants and other species, inserted genes may not function as expected, more than one copy may be inserted and natural genes may be disrupted. In subsequent generations effects can surface, including the expression of formerly unexpressed proteins or insertional mutations.<sup>9</sup> Unpredictable mutations and genetic changes also occur in conventional breeding, but less often.<sup>10</sup> These low success rates may improve over time, although this has not occurred in the twenty years since animals were first genetically modified or in the four years since cloning began.
- 13 The first genetically modified animals were transgenic mice, created in the early 1980s. Transgenic animals possess active copies of one or more genes that have been inserted into them from another individual from the same or a different species. It is also possible to stop production of a protein by a particular gene - 'knocking out' the gene function; or to insert -

7 Wall RJ. Transgenic livestock: progress and prospects for the future. *Theriogenology* 45:57-68,1996.

8 Hill RJ *et al.* Clinical and pathologic features of cloned transgenic calves and fetuses (13 case studies). *Theriogenology* 51: 1451-1465, 1999. Garry FB *et al.* Postnatal characteristics of calves produced by nuclear transfer cloning. *Theriogenology* 45:141-152, 1996. Pennisi E & Vogel G. Clones a hard act to follow. *Science* 288:1722-1727, 2000. Wilmut *et al.* Nuclear transfer in the production of transgenic farm animals, in *Transgenic Animals in Agriculture*, Murray JD *et al* (eds). CABI International, pp. 67-78, 1999.

9 Butler SP *et al.* Current progress in the production of recombinant human fibrogin in the milk of transgenic animals. *Thrombosis and Haemostasis* 78: 537-542, 1997.

10 Some insertional mutations may be damaging to the animal, although it is likely that many would be without effect. The effect of transgenes through their ability to cause insertional mutations needs to be assessed against the baseline level of insertional mutation through natural causes.

'knock in' - genetic material to a specific gene to modify the type of protein produced by the gene or the way the protein is regulated. Chromosome engineering allows large-scale rearrangements of DNA in an animal. All of these techniques are commonly referred to as 'genetic modification' or 'GM' and the animals produced are termed 'GM animals' and this is how the term should be understood in our report. We have also considered animals cloned by cell nuclear transfer not involving genetic modification<sup>11</sup> (referred to in this report simply as 'cloned animals'). Animals that are not genetically modified or cloned are termed 'conventional animals'<sup>12</sup> in the report.

## **APPLICATIONS OF GM AND CLONING TO ANIMALS**

- 14 The Royal Society report on GM animals<sup>13</sup> and the Animal Procedures Committee report on Biotechnology<sup>14</sup> set out in detail the various applications of genetic modification under way at present or expected in coming years. We have not attempted to duplicate this effort but have instead summarised the principal present and expected applications of the technology.

### **Medical research**

- 15 The principal application of genetic biotechnology to animals at present is for medical and biological research, largely drawing on information derived from human and animal genome sequences. At present the vast majority (98 per cent) of the GM animals involved in research under the 1986 Animals (Scientific Procedures) Act are mice. There are three main aspects to this research: the use of animals as models for specific human diseases; better understanding of basic human biology; and testing substances for toxicity. Between 1990 and 2001, the number of experimental procedures involving transgenic/GM animals<sup>15</sup> rose from some 50,000 to over 630,000.<sup>16</sup> About seventy percent of the current procedures involving GM animals are comprised of breeding to maintain populations with a specific genetic modification.<sup>17</sup>

11 The relevant European Directives define a genetically modified organism (GMO) as an organism in which 'the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'. The Directives exclude from the definition of GMOs the following processes: mutagenesis (the random mutation of genes by deliberate use of a virus, chemical or radiation), in vitro fertilisation, natural processes such as conjugation, transduction and transformation, and polyploidy induction, providing no genetically modified micro-organisms or recombinant nucleic molecules are involved in this process. Self-cloned (hereafter, 'cloned') animals are animals that have been created by transferring a nucleus from the cell of an animal into an egg cell from which the nucleus has been removed. Dolly the sheep was created in this way. According to the Health and Safety Executive and DEFRA, a cloned animal, unless it was judged that it posed a particular threat to human health, is exempt from the Contained Use Regulations 2000 (implementing in the UK the European Directive 98/81/EC). Cloned animals are also exempt from the Directive on Deliberate Release into the Environment (2001/18/EC). In this report, we distinguish between GM animals and cloned animals, as does the Royal Society report, *The use of genetically modified animals*.

12 Non-GM animals produced using marker-assisted breeding, where knowledge of the animal's genome makes it easier to breed for desired characteristics, are considered as 'conventional' in this context.

13 Royal Society. *The use of genetically modified animals*. May 2001.

14 Animal Procedures Committee. *Report on Biotechnology*. July 2001. The Animal Procedures Committee's reports on biotechnology and openness can be viewed at [www.apc.gov.uk](http://www.apc.gov.uk).

15 In the Home Office statistics, the category of 'transgenic' animals was added in 1990 but was replaced in 1995 with the wider category of 'GM' animals.

16 Home Office, *Statistics of Scientific Procedures on Living Animals*, 23 July 2002 (Cmd 5581). Over the same period the total number of procedures involving animals declined overall from some 3.2 million to just over 2.6 million, due to a decline in the number of procedures involving genetically normal animals. But the overall decline has flattened out (numbers in fact increased slightly between 1999 and 2000) due to the rising number of procedures involving GM animals.

17 The House of Lords Select Committee on Animals in Scientific Procedures has recommended that animals from genetically modified strains which are bred but not otherwise used in regulated procedures should be excluded from the Home Office statistics, provided that they have no characteristics with adverse welfare implications. House of Lords. *Select Committee on Animals in Scientific Procedures*. July 2002. Paragraph 8.16, at [www.publications.parliament.uk/pa/ld200102/ldselect/danimal/150/150.pdf](http://www.publications.parliament.uk/pa/ld200102/ldselect/danimal/150/150.pdf)

About a quarter of the procedures involve using animals as human disease models or research into gene function. The remaining five percent are applied work, such as toxicity testing. The number of GM animals involved is expected to rise substantially over the next few years, as the functions of new genes identified in genome sequencing projects are analysed.

- 16 Mice and other animals can be genetically modified to provide **models of human diseases**. Animal models are used because of the overall high similarity between mouse and human genomes coupled with common fundamental characteristics of cellular mechanisms. The object is to research the underlying pathology of the disease and to test potential treatments.
- 17 In addition to researching specific diseases and possible cures, the fact that mice and other animals share a great number of genes with humans is also being employed in **research to understand the fundamental biology of humans**. The decoding of the entire human genome sequence has emphasised how little we understand about the function of most of our genes. Mice, fruit flies,<sup>18</sup> zebrafish, the South African claw-toed frog<sup>19</sup> and a nematode worm<sup>20</sup> are among the main organisms involved in this fundamental research. Experiments include knocking out a particular gene that is shared by an animal and humans to improve understanding of the function of the gene.
- 18 The third main area of research involving GM animals is a development of the use of conventional animals to **test the toxicity of chemicals and drugs**, for example whether they cause cancer. Some rodents have been genetically modified so that if a mutation in a gene occurs, the change can be easily detected. This can be achieved, for example, by the modified genes, when removed from the animal and introduced into yeast cells, causing the yeast cells to change colour. Other rodents have been modified to be much more sensitive to carcinogens than their conventional relatives, so that they will develop cancer much faster if a carcinogen is present in a test substance. The advantage of using the sensitised GM animals is that safety testing of new products may be completed more quickly and with fewer animals than in conventional tests.

### Faster-growing fish

- 19 Many species of fish have been genetically modified in the laboratory to produce a wide variety of traits. One US company has developed a GM salmon known as AquaAdvantage®. This fish has been genetically modified to grow at two to three times the rate of unmodified salmon. An application for a licence for commercial use of such salmon has been made for marketing approval to the US Food and Drug Administration and the company is reported to expect that if the application is successful the fish will reach US supermarkets within four to six years.<sup>21</sup> Other fish, including trout, carp, catfish and tilapia have been the subject of research. Subject to regulatory approval, salmon would appear to be the closest to reaching the US market. There are significant environmental concerns relating to the intended or unintended release into the marine environment of faster-growing fish or fish modified in other ways, which we discuss further in Part 2.

<sup>18</sup> *Drosophila melanogaster*

<sup>19</sup> *Xenopus laevis*

<sup>20</sup> *Caenorhabditis elegans*

<sup>21</sup> Biotechnology Industry Organization. *Editors and Reporters Guide to Biotechnology: Products on the Market* ([www.bio.org/er/agri\\_products.asp](http://www.bio.org/er/agri_products.asp))

## Pharming

- 20 'Pharming' is the production of pharmaceutical products in animals, usually farm animals, which have been modified for the purpose. The pharmaceutical product is synthesised by the animals and commonly expressed in their milk, urine or eggs. Some fifty products are in development, including treatments for Pompe's disease, hereditary angioedema, heart attacks, cystic fibrosis and haemophilia. Many genetic illnesses and syndromes are caused by absence of a single protein (usually an enzyme). In some cases this can be effectively or completely treated by providing the missing enzyme, normally by injection. In other cases a factor can be provided to treat non-genetic conditions (e.g. bleeding and clotting complications, heart attack). PPL Pharmaceuticals (Roslin), for example, have a flock of some two thousand GM sheep in Scotland producing a pharmed protein called alpha-1-antitrypsin (known generally as AAT) that is in clinical trials at present. PPL and Bayer hope to achieve regulatory approval for the product in 2007.<sup>22</sup> The product is intended to treat hereditary emphysema. PPL are also working on a potential treatment for cystic fibrosis patients.
- 21 Animals are also being modified to express non-pharmaceutical products. For example, goats have been genetically engineered to express spiders' silk in their milk.<sup>23</sup> The aim would be to harvest the silk, which has exceptional strength and other properties, for military body armour and for medical and other commercial purposes. There is work under way on 'functional foods or 'nutraceuticals' with specific enhanced properties. For example there are three main proposals for the transgenic modification of milk for the dairy industry: 'humanising' cows' milk (primarily to enhance the properties of infant formula); increasing the proportion of the more valuable protein component; and reducing lactose to increase potential markets for milk.<sup>24</sup>

## DNA vaccines

- 22 An area of genetic biotechnology that is likely to increase over the next few years is the use of DNA vaccines. Animals are vaccinated not with the protein that induces an immune response but instead with a piece of DNA that encodes such a protein. This has the potential advantage of being simpler to produce and prolonging the exposure of the animal's immune system to the immunogen and thereby inducing more effective immunity. Importantly, the foreign DNA is not expected to integrate into the host's genome and so the vaccinated animal is not genetically modified.

## GM insects

- 23 There is considerable interest in using biotechnology to control insects which spread disease.<sup>25</sup> Techniques under development include using genetic manipulation to improve an existing method of reducing the numbers of insects in a particular area, which involves releasing many

<sup>22</sup> PPL and Bayer earlier had been working to a shorter timescale but announced in March 2002 that this would slip to 2007, although they would be seeking to expedite the timetable.

<sup>23</sup> In the US, by Nexia Biotechnologies (Nexia press releases: [www.nexiabiotech.com](http://www.nexiabiotech.com))

<sup>24</sup> Zeulke KA. Transgenic modification of cows' milk for value added processing. *Reproduction Fertility Development* 10: 671-676, 1998. Maga EA & Murray JD. Mammary gland expression of transgenes and the potential for altering the properties of milk.

*Biotechnology* 13: 1452-1457, 1995. Karatzas CN & Turner JD. Toward altering milk composition by genetic manipulation: current status and challenges. *Journal of Dairy Science* 80: 2225-2232, 1997.

<sup>25</sup> Alphey, LS. *Current and likely future uses of GM insects*. Note for AEBC, 2001.

sterile male insects into a local population.<sup>26</sup> Sterilisation is currently achieved by irradiation, but this has the side effect of making the insects ten times less vigorous and so the control process less efficient.

- 24 Much research has been undertaken in relation to mosquitoes, which carry the malaria parasite. The aim is to genetically modify mosquitoes to be resistant to the malaria parasite and to release them into the environment to replace the existing, susceptible, wild population. Recently, mosquitoes were genetically modified to be less able to transmit the disease.<sup>27</sup> It may be possible to apply these technologies to a wide range of insect disease-carriers and to other invertebrates such as nematodes.<sup>28</sup> The aim would be to replace populations of insects which spread disease to humans, livestock or plants with almost identical populations which do not cause this damage.
- 25 The risks which have been noted in connection with GM insects include the unpredictability of the effects of widespread release of GM insects into a wild population and the possibility that the beneficial genetic modification might mutate or undergo partial deletion. There might be undesirable unintended behavioural changes in modified insects (e.g. increased aggressiveness in biting insects). The use of 'gene drivers'<sup>29</sup> to spread a particular genetic modification through an insect population would be an irreversible strategy with implications for whole populations and even species. The environmental and biosafety issues relating to the use of gene drivers would be significant and any release would need extensive justification and planning.

### Farm animals

- 26 There are no GM farm animals (except for those in biopharming) in commercial production at present in the UK. We understand that in the United Kingdom, GM animals produced for human consumption would, if given regulatory approval, be some ten years from the market.<sup>30</sup> Aside from the question of the public acceptability of GM livestock entering human food supplies, there are practical obstacles. These include the expense of the process, due in part to only a small proportion in many cases of modified embryos surviving into adulthood. Knowledge of farm animal genomes is incomplete. The longer breeding cycles of these animals can limit the pace at which research can move forward. Moreover, production of farm animals in the UK is not generally financially rewarding at present, so is unlikely to attract venture capital funding in the same way as medical biotechnology research.
- 27 Small numbers of cloned farm animals, however, have been produced overseas. The cloning process is expensive and inefficient, so commercial agricultural applications to date have been limited to high-value individual farm animals. High-performing bulls have been cloned under commercial licence in Australia for sale to China and elsewhere. A few cloned calves of prize cattle are reported to have been sold at auction in the US.<sup>31</sup>

26 Thomas DD, Donnelly CA, Wood RJ & Alphey LS. Insect population control using a dominant, repressible, lethal genetic system. *Science* 287(5462), Mar 31 2000, pp. 2474-6.

27 Ito J *et al.* Transgenic anopheline mosquitoes impaired in transmission of a malaria parasite. *Nature*, 417:452-455, 2002.

28 Nematodes are worms which can cause plant or animal disease.

29 For example, autonomous transposable elements or *Wolbachia* (bacteria living in insect cells).

30 Royal Society. *The use of genetically modified animals*. May 2001, paragraph 72.

31 Cyagra press releases 5 July and 31 Dec 2001 ([www.cyagra.com](http://www.cyagra.com)); and BBC, *Commercial cloning hits China*, [news.bbc.co.uk/1/hi/English/sci/tech/newsid\\_1779000/1779775.stm](http://news.bbc.co.uk/1/hi/English/sci/tech/newsid_1779000/1779775.stm)

- 28 A number of applications of genetic modification to farm animals may be possible. As with fish, it may be possible, for example, to use genetic modification to create faster growing livestock or produce leaner meat.<sup>32</sup> Other applications would include engineering resistance to specific infectious diseases within the animal population. An example is Marek's disease in poultry, a virus-induced lymphatic cancer, which is clearly detrimental to the birds' welfare and costs the UK poultry industry alone some £100m a year. It might be possible to make animals resistant to infectious diseases that are also human health risks such as Salmonella in poultry or to produce BSE-resistant cows or scrapie-resistant sheep. The large number of breeds of cattle and extent of subsequent breeding to spread the trait through the national herd or flock, however, would make the latter two examples ambitious undertakings. A further example relates to high agricultural value strains of cows which cannot be maintained successfully in sub-Saharan Africa. This problem could be overcome, it is claimed, by introducing disease resistance genes from local cattle.<sup>33</sup>
- 29 It is further claimed that genetic modification could be used to improve farm animal welfare by correcting physiological problems which have arisen as a result of conventional selective breeding.<sup>34</sup> Increased knowledge of animal genome sequences has the potential to allow some of the same effects to be achieved by identifying effective genetic maps that will improve marker-assisted breeding techniques.<sup>35</sup>
- 30 As noted above (paragraph 12) despite the aspirations for the application of modern biotechnology to agricultural animals, farm animal species have proved technically difficult to genetically modify and clone. Not only are there technical difficulties to be overcome, but modifying an animal's physiology to improve performance may prove very difficult without causing other adverse effects as a consequence.<sup>36</sup> These hurdles illustrate that although there is potential for genetic modification to bring about rapid changes, the whole process, including the necessary fundamental research that underpins a specific modification, remains a slow and complex process.

## **Pets**

- 31 There are no widespread applications of genetic modification to pets ('companion animals') at present. The planned genetic modification by a small American company<sup>37</sup> of cats so that the animals do not provoke a human allergic reaction has recently received publicity, however, and the company has claimed that such cats could be produced by 2003, subject to commercial funding.<sup>38</sup>

<sup>32</sup> Early attempts in the 1980s to produce GM farm animals with decreased carcass fat content resulted in the so-called Beltsville pigs, which experienced seriously reduced welfare. However, attempts to improve this approach have continued e.g. see Nottle MB et al. Production and analysis of transgenic pigs containing a metallothionein porcine growth hormone gene construct in *Transgenic Animals in Agriculture*, Murray JD et al (eds). CABI International, 1999, pp. 145-156. An analogous approach is discussed by Pursell VG et al in Expression of insulin-like growth factor 1 in skeletal muscle of transgenic swine, Murray J D et al, 1999, pp. 131-144.

<sup>33</sup> Royal Society. *The use of genetically modified animals*. May 2001

<sup>34</sup> Farm Animal Welfare Council. *Submission to the AEBC*. 6 February 2001

<sup>35</sup> Vernon Barber, National Farmers Union. *Evidence to AEBC*. 30 January 2001

<sup>36</sup> Ward KA et al. The utilisation of bacterial genes to modify domestic animal biotechnology. In *Transgenic Animals in Agriculture*, Murray JD et al (eds), CABI International, 1999, pp. 157-176.

<sup>37</sup> Transgenic Pets of Syracuse, NY State. The company is reportedly collaborating with the Transgenic Animal Facility at the University of Connecticut and is seeking funding to carry out this work.

<sup>38</sup> See, for example, BBC, *Designer Cat Controversy*, at [news.bbc.co.uk/1/hi/english/sci/tech/newsid\\_1411000/1411802.stm](http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1411000/1411802.stm)

- 32 The first cloned domestic cat was produced in the United States in December 2001 by researchers at Texas A&M University. The ‘Missyplicity’ research project funded by a US company, Genetic Savings and Clone (GSC), to clone a specific (now deceased) pet dog, called Missy, has been under way for some time. Dogs have not yet been successfully cloned. GSC also funded the cloned cat project. GSC and other companies have stored the DNA of other pets at the request and expense of their owners against the day when it may be possible to clone those animals.<sup>39</sup> Genetic modification has also been mooted as a way of changing animal behaviour although the genetic complexity underlying behaviour means that this is at present technically impracticable. We discuss this last possibility further in Part 1.5.
- 33 In the context of the various possible applications discussed above, some people argue that it would always be preferable to employ means other than genetic modification, particularly conventional or marker-assisted breeding, to achieve the various desired changes to farm animals and pets. Others view GM and cloning as part of a spectrum of technologies available to animal breeders and argue that the purpose of the modification is a more significant criterion for determining acceptability than the technique used to achieve it.

### **Xenotransplantation**

- 34 This is the transplantation of tissue and organs between different species, and in particular the transplantation of animal tissue into humans. There is a serious shortage of human organ donors and some animals, particularly pigs, are being examined as a potential source of suitable organs or cells, genetically modified to reduce the chance of rejection by humans. The recent successful production of cloned pigs is a further step towards efficient genetic modification of pigs and as such is aimed at bringing xenotransplantation closer. There is debate about whether sufficient other necessary progress will have been made to allow successful transplants from GM animals in the next five to ten years. Besides organ rejection, there remain serious concerns about the possible transfer of animal viruses to humans that will have to be addressed before the technology could be applied; and there are also concerns about physiological compatibility.<sup>40</sup>

### **Sporting animals**

- 35 The breeding of racehorses is regulated by the horseracing industry, which stipulates an entirely natural process from fertilization to birth of the horse. This effectively rules out GM and cloning at present in racehorse breeding (and artificial insemination).
- 36 Other parts of the equestrian sports industry do not have the same strict rules on breeding as exist for thoroughbred racehorses. For these horses, the industry rules are silent on the application of GM and cloning. This is the same for greyhound racing. The application of GM to sporting animals does not appear to be a major area of activity at present, although there is some interest in the possibilities.<sup>41</sup> Genetics Savings and Clone for one is investing in research into cloning horses.<sup>42</sup>

39 For example, Advanced Cell Technology (‘Companion Animal Cell Banking’ at [www.advancedcell.com](http://www.advancedcell.com))

40 These issues are considered by the UK Xenotransplantation Interim Regulatory Authority.

41 The Equine Fertility Unit in Newmarket produced Europe’s first foals through in vitro fertilisation in 2001. The technique, it was claimed, could make it easier to produce genetically modified horses with the aim of improving their performance. ([http://news.bbc.co.uk/1/hi/english/sci/tech/newsid\\_1337000/1337276.stm](http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1337000/1337276.stm)).

42 See [www.savingsandclone.com](http://www.savingsandclone.com)

- 37 Genetic modification of sporting animals could conceivably become an issue for industries using sporting animals. Just as a lot of effort is put into detecting and preventing doping of animals (and, indeed, in human sports) so trying to stop genetic modification of sporting animals could come to the fore. If so, this might drive research to find practicable ways to detect particular modifications in animals.

## **PART 1.4**

### **PUBLIC ATTITUDES TO ANIMALS**

### **AND GENETIC BIOTECHNOLOGY**

- 38 Having surveyed possible applications of GM and cloning to animals, we now look at what we have learnt about public attitudes to what is going on and what appears to be coming over the horizon. From the social research we commissioned, a number of important points emerged which we have grouped as follows: attitudes to animals; attitudes to GM and cloning; and attitudes to applying the technology to animals.
- 39 In this context, we understand ‘attitudes’ to stand as surrogates for people’s values at the time of the research discussions - yielding, effectively, snapshots of their moral and social stances towards the issues raised. History suggests, of course, that such stances, and even the ethical concerns underpinning them, may evolve over time, in interaction with events, experience, and wider private and public discussions.

## **ATTITUDES TO ANIMALS**

- 40 Both the Macnaghten and Breakwell studies confirmed that in the UK there are widespread strong feelings about animal use generally and animal welfare in particular. The Macnaghten study involved people who collectively had a wide range of everyday experiences of animals, as pets, as wildlife, as prey, as working partners and as livestock. The findings suggest that people’s attitudes to animals and the uses they make of them are complex. The Macnaghten report found that people tended to adopt divergent ways of talking about animals depending on the nature of their relationship with animals, although the differences should not be over-emphasised. Farmers, for example, were more likely to view genetic modification of farm animals as the next stage of selective breeding, although sceptical that it would deliver tangible benefits to them.
- 41 The Macnaghten report found that ‘many people have close, affective relationships with animals in domestic and other contexts.’ It also noted that people recognised ‘frequent personal contradictions in their behaviours towards animals, moving between close, even intimate and inter-dependent family connections’ and using animals for food, clothing and in laboratories. Moreover, the researchers found that ‘a degree of ‘denial’, and even hypocrisy, in this regard is frequently acknowledged. Such reactions appear to signal shifting social awareness of the tensions between ‘moral’ and ‘instrumental’ approaches to animals in modern society.’

- 42 Professor Breakwell found that existing research showed evidence that people had a complex pattern of reasoning, knowledge and values. People were aware of inconsistencies and ambivalence and wanted to form opinions based on facts when making judgments about what is justifiable in society's relationships with animals.

## ATTITUDES TO GENETIC BIOTECHNOLOGY

- 43 In 1996, sixty percent of UK citizens interviewed in the European Commission's Eurobarometer poll tended to agree with the statement that 'only traditional breeding methods should be used, rather than changing the hereditary characteristics of plants and animals through genetic technology'.<sup>43</sup> In the same poll, on the other hand, a majority tended to agree that developing GM animals for laboratory research, such as a mouse that has genes that cause it to develop cancer, was useful; at the same time a majority also tended to think that this was morally unacceptable.
- 44 A Eurobarometer poll<sup>44</sup> in 1999 suggested some public misgivings in the UK and elsewhere in Europe about the cloning of animals. A majority of respondents rejected the cloning of animals for medical purposes, although there was moderate support for the cloning of human cells for the same purpose.
- 45 These two examples, cited in the Breakwell study, seem to illustrate that people's attitudes to genetic biotechnology in relation to animals bears comparison with attitudes to applying genetic biotechnology to crops. There is a spectrum of views about GM and cloning, as we noted in our first report, *Crops on Trial*. Some of the changes are perceived to be 'unnatural' in some sense. At one end of the spectrum, 'GM technology is not simply an advance in molecular biology, but a major and irreversible watershed in human intervention in nature. Seen from this perspective, the specific concerns expressed about the uncertainties and limitations of present GM knowledge often demonstrate a wider ontological unease<sup>45</sup> at the hubris of such fundamental human manipulation of nature.' At the other end of the spectrum is the view that genetic modification or cloning represents a progressive evolution from selective breeding in animal production and is not qualitatively different.<sup>46</sup>
- 46 In the Macnaghten study, the researchers sought to tease out whether genetic modification in itself is at issue in the public mind; and the nature of public views about applying genetic biotechnology, including genetic modification, to animals. They found that people's views on genetic biotechnology developments built on their attitudes to existing practices and relationships involving animals. The research also found that most people regarded the direct genetic modification of animals as both 'new' and 'unnatural'. Although few people rejected the use of the technology out of hand, people expressed considerable concern about the pace of developments, the nature of the techniques used, and they anticipated unforeseen mistakes arising from use of the technology. The researchers found that people commonly were wary of 'going against nature', a term that the researchers considered was key to the distinctiveness of people's concerns about animals and biotechnology.

43 Eurobarometer 46.1.

44 Eurobarometer 52.1 ([www.europa.eu.int](http://www.europa.eu.int))

45 An unease relating to the intrinsic nature and essence of things, which political science research suggests is often expressed metaphorically.

46 AEBC. *Crops on Trial*. September 2001, particularly paragraphs 77-87. Available at [www.aebc.gov.uk](http://www.aebc.gov.uk)

- 47 The researchers found that people's concerns about biotechnology included a concern for the 'intrinsic character of animals, including the need for animals to retain their integrity'. Concerns about going against nature, then, seem to relate both to a concern for the integrity of the nature of the animal itself and also to perceived potential wider undesirable effects resulting from changes made to the animal.

### **WHEN IS IT ACCEPTABLE TO APPLY GM AND CLONING TO ANIMALS?**

- 48 The Macnaghten report found that in relation to animal experimentation in general (not only involving GM and cloning) people's attitude depended critically on the purpose of the research. Prospective medical applications made people less uncomfortable than cosmetic applications, although there appeared to be 'an emerging acknowledgement of the difficulty of maintaining such clear-cut distinctions.' Key conditions for applying GM to animals included the requirement to demonstrate a genuine and authentic need for undertaking such procedures, commensurate with people's considerable concerns about the technology.
- 49 As noted earlier, the vast majority of GM animals at present are produced for research purposes. The Macnaghten study suggested that most people have only a limited understanding of the nature and extent of experimentation on animals in the UK. Most people agreed, in response to the suggestion that genetic biotechnology may require a substantial increase in animal testing, that such additional testing of animals may well be justified, especially on health grounds, but they would want to judge the evidence for themselves. In the light of such an increase, 'perceptions of the purposes of the research or exploitation processes involved' assumed significance. Hence, 'the question of justification became a more urgent matter, demonstrable not just to expert committees but also to the public at large.' This finding points, among other things, to the importance of transparency in decision-making in this area and to the importance of fostering greater social debate, involving scientists, citizens and others, in relation to the use of GM animals for research.
- 50 The conclusions drawn by Professor Breakwell from existing research were that the main bases of people's judgement are whether the technology is 'useful' and 'ethical'. Perceptions of moral unacceptability 'act as a veto' in people's attitudes to what may be done with animals. These criteria are applied even if the perceived risk of particular application to human health and the environment is low. Surveys supported the finding in the Macnaghten report that medical uses of GM animals were generally more acceptable than others (although a medical use certainly does not lead to automatic public acceptance). When considering whether a biotechnological development is right or wrong, the possibility of harm to animals is an important consideration.
- 51 Other data also suggest that public views about developments in the field are tied up with their attitudes to the regulatory system and in particular the parties responsible for regulating activities in these areas. A MORI survey undertaken in the UK for Government in 1998/99 found that only 35 percent of those surveyed trusted Governments to make decisions on their behalf in the regulation of the biological sciences.<sup>47</sup> A recently published study, funded by the

<sup>47</sup> MORI. *The Public Consultation on Developments in the Biosciences*, December 1998-April 1999, p. 71.

European Commission, of public perceptions of agricultural biotechnologies in a number of EU countries found widespread public unease about patterns of political and regulatory oversight in this area.<sup>48</sup> Public concerns expressed in the focus groups used in the research were mostly based 'on empirical lay knowledge about the past behaviour of institutions responsible for the development and regulation of technical innovations and risks, supported by numerous commonly shared experiences...In this context BSE was not regarded as an exception. Rather...[it was] an exemplary case demonstrating the normal behaviour of such institutions.'<sup>49</sup> We explored the implications of public mistrust of Government as a regulator in *Crops on Trial*.<sup>50</sup>

- 52 The Macnaghten research brings out this point. In the course of the discussions, the researchers found that:

'Repeatedly, the crises over BSE and GM foods were invoked in support of suggestions that institutions of science, government and agri-business were not to be trusted as key institutions responsible for overseeing such innovations - dependent as they were on taking animals further away from their nature - in a responsible and ethically sensitive fashion. Perceiving such institutions as being 'in denial' of such realities exacerbated people's sense of the likelihood of subsequent retribution, of 'throw backs', of 'nature striking back', and of 'us getting carried away without thinking about the repercussions.'

The researchers found that the main message for the Government about GM and cloning and animals from participants in the research was not to reject the technology out of hand, but 'to proceed cautiously, slowly, openly, and with recognition of the scale and scope of what was being undertaken.'

- 53 In summary, unease about political and regulatory oversight in a field perceived as driven largely by scientific and commercial priorities is an important characteristic of public views about GM and cloning and animals. So is concern for the 'integrity' of animals. It may be that some people's concerns about applying GM to plants are exacerbated in relation to animals, at least the 'higher' animals, due to people's existing relationships with animals and the consequent respect many people have for the integrity of animals' natures. There appears at this stage to be relatively little outright rejection of genetic biotechnology in relation to animals, but considerable concerns about the potential nature and speed of modifications made to animals and the possibility of unforeseen mistakes. People believe there should be clear justification of applications of the technology and want a transparent, and above all trustworthy, regulatory system.

48 Marris C, Wynne B, Simmons P, Weldon S. *Public Perceptions of Agricultural Biotechnologies in Europe*. May 2002. (Report available at [www.pabe.net](http://www.pabe.net))

49 Ibid, executive summary, p. 5.

50 AEBC. *Crops on Trial*. September 2001.

## **PART 1.5**

### **WHAT IS DIFFERENT ABOUT GENETIC BIOTECHNOLOGY?**

- 54 The information about public views above suggests that the application of GM and cloning to animals should be examined in the context of society's wider relationships to animals and to existing practices, because people's attitudes are mediated by their existing relationships with animals. It also seems likely that few members of the public are aware of all the constituent parts of the regulatory system already in place.
- 55 We started by looking at the scope of present regulation to deal with present and likely future developments in GM and cloning and people's likely views about the developments. Our presumption has been that it would be better not to create separate regulation to deal with GM and cloning where the existing system is adequate. To test out the applicability of this approach, it is necessary first to examine the differences and similarities between the uses of GM and cloning and conventional practices involving animals.

### **ENVIRONMENTAL IMPACT**

- 56 As noted earlier, there are no GM farm animals, other than those used for biopharming, in commercial production in the UK. The environmental impact of research animals, whether GM or not, is not currently a major issue because the animals are kept in contained premises.<sup>51</sup>
- 57 It is difficult at present to see any new issue for biodiversity or environmental impact from any commercialisation of GM or cloned farm animals unless, perhaps, genetic biotechnology was used to produce animals which could thrive in habitats not much used at present by conventional livestock. Livestock farming of course has significant environmental impacts, but these impacts would not be specific to GM and cloning applications. Present regulations would nonetheless require assessment of the environmental impact of a GM animal, including a GM farm animal, prior to commercialisation. The possible environmental impact of commercialisation of GM fish, on the other hand, does raise more serious environmental issues (see part 2). The release of GM insects would also require particular care and attention.
- 58 In principle, farm animals might be genetically modified to have a less adverse environmental impact. For example, ruminants might be modified to produce less greenhouse gases. Environmental problems from livestock production however might equally be addressed by conventional means.

<sup>51</sup> 'Contained use' is defined as any activity in which organisms are genetically modified or in which GMOs are cultured, stored, used, transported, destroyed or disposed of and where barriers are used to limit contact of the GMOs with humans and with the environment. The degree of limitation of contact and choice of appropriate measures must always be determined by the risk assessment. For biopharmed mammals, containment may mean securely fenced fields: contained use need not always involve keeping animals indoors. See the publication by the Health and Safety Executive: *A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000*.

## ANIMALS' NATURES

- 59 Are the changes which could potentially be made to animals by GM grounds for considering GM animals quite differently from conventional animals? Our social research suggested a strong regard for the 'integrity' of an animal's nature. Violating this is often seen as fundamentally objectionable.
- 60 Is this possibility in fact peculiar to genetic biotechnology? It would seem not. The Banner report cites the case of the production of turkeys of such a size as to be incapable of natural breeding without risk of body damage to the hen.<sup>52</sup> The current Farm Animal Welfare Council (FAWC) Welfare Code recommends saddles for hens and toe cutting of male turkeys to prevent injury during natural mating. The FAWC report on turkeys<sup>53</sup> did not find any particular welfare problems arising from the widespread practice of using artificial insemination. But the Banner report found that even so, 'the breeding of birds who are physically incapable of engaging in behaviour which is natural to them is fundamentally objectionable'.<sup>54</sup>
- 61 Genetic modification does, however, give rise to greater public concern about the possibilities of changes to an animal's nature, principally because of the perceived possible speed and types of change allowed by genetic modification. Some, at present hypothetical, examples about the possible modification of animal behaviour may help to illustrate this concern and its implications.
- 62 One example would be the possibility of using GM to reduce the hunting instinct in domestic cats. This is a theoretical example: the technical barriers to achieving it are very great at present. Nor are we aware of active scientific work to seek to achieve it. But if such a development ever became technically feasible and a commercially viable proposition, in thinking about whether it was desirable, the possible effect of an increase in the numbers of songbirds in the United Kingdom, where cats are thought to kill significant numbers of such birds every year, might be thought relevant. Any welfare implications for the modified cats would also need to be considered.
- 63 But the question is whether it would be appropriate to change the fundamental nature of the animal in this way, regardless of the putative purpose. Some would argue that although cats, like dogs, have been selectively bred over many generations so that modern cats look and behave quite differently from their wild ancestors, the hunting instinct should remain as a necessary part of a cat's nature. Others might argue that further change is acceptable since cats have already lost many 'natural' characteristics in the course of domestication.
- 64 The same point emerges in relation to a sometimes discussed theoretical application of biotechnology to the livestock industry, namely the use of genetic modification to reduce the sentience of farm animals in order to increase those animals' ability to withstand a stressful management regime.<sup>55</sup> The production of a line of animals with reduced sentience is purely hypothetical, not least because there is insufficient knowledge about how genes control behaviour to be able to design such animals (as with reducing the hunting instinct in cats).

<sup>52</sup> MAFF, *Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals*, 1995 ('the Banner report'), p. 27, paragraph 4.45.

<sup>53</sup> FAWC, *Report on the Welfare of Turkeys*, 1995.

<sup>54</sup> Banner report, p. 27, paragraph 4.45.

<sup>55</sup> This theoretical case is discussed the Banner report, pp. 15-17.

- 65 The Banner report considered that development of an animal with reduced sentience was objectionable in principle because it would stop the farm animal living in accordance with its natural end in life and being a proper example of its species, regardless of whether the modified animal experienced suffering. It is important to note that this point would not be confined solely to genetic biotechnology. Selective breeding could in theory produce similar results. Some would argue that the long process of domestication of animals has already at least partially done so.
- 66 Moreover, animal behaviour can be modified - for good or ill - by means other than GM. Witness the recently created 'Roborat' which is a normal rat with electrodes implanted in its brain which allow a human to remotely control the direction of movement of the animal.<sup>56</sup> This technique might at some point be proposed as a means of controlling the activity of farm livestock.
- 67 Thinking about modification of animal behaviour raises difficult and complex issues. It is right in principle that decision-making about what may be done to animals should take account of the view, emerging from our social research, that there may be intrinsic objections to certain fundamental changes to an animal's nature. Otherwise, it might be thought that absolutely anything is permissible, in any circumstances, in relation to the creation of new strains of animal, whether by genetic modification or by other means.

## **CLONING**

- 68 Cloning of adult animals is something that has only become possible through genetic biotechnology. Unlike some of the other examples cited above, the same result could not be achieved through conventional techniques. There are welfare considerations at present associated with the procedures for production of cloned animals.
- 69 There is a question of whether cloning causes surviving animals to have inherent defects which impinge on their welfare. Professor Ian Wilmut, the leader of the team that produced Dolly, the cloned sheep that developed arthritis at a relatively young age, has stated that 'it is not possible to know if her condition is in any way a result of her being a clone. However, this occurrence emphasises the need to monitor the health of a considerable number of clones throughout their expected life span to discover if any conditions normally associated with age develop in unusually young animals.'<sup>57</sup> In its assessment of the implications of cloning farm animals, the Farm Animal Welfare Council<sup>58</sup> did not rule out the use of cloning as a matter of principle but recommended that there should be adequate post-commercialisation monitoring of cloned animals for any unforeseen welfare or other effects. We support this recommendation (see Part 2.2 below).
- 70 The technology is capable in principle of being applied to a variety of animals for quite different purposes. A pet cat has been cloned. Sheep and goats have been cloned for pharmaceutical production, where there is a possible purpose in terms of potential human benefit from the production of new medicines and from creating economic activity.

<sup>56</sup> The researchers suggested that roborats could be used, for example, to find people buried in rubble, rats being able to squeeze into much smaller spaces than can dogs or humans.

<sup>57</sup> Roslin Institute. *News Note 01-02*. January 2002. Available at [www.roslin.ac.uk](http://www.roslin.ac.uk)

<sup>58</sup> FAWC. *Report on the Implications of Cloning for the Welfare of Farmed Livestock*. December 1998.

- 71 We believe that the purpose matters, and we endorse the recommendation of the Animal Procedures Committee (APC) that ‘no licences should be issued for trivial objectives, such as the creation or duplication of favourite pets, or of animals intended as toys, fashion accessories or the like, and the Home Office should consider the motives and character of would-be licensees’.<sup>59</sup> The conclusion reached by the APC is that replacing a favourite pet is not sufficient justification for embarking on a cloning programme, even though cloning may not be considered to unacceptably alter an animal’s nature in the same way as some other changes, for example, reduced sentience.
- 72 In the future, if no or minimal welfare considerations applied because cloning of a particular species had become more efficient, some may argue that cloning of pets should be allowed, on the grounds that it is not morally so different from other practices with pets. It seems likely that the cloning of pets at that point would be considered in the context of other permitted practices, including selective breeding.

### **SPEED OF CHANGE MADE POSSIBLE BY GENETIC MODIFICATION**

- 73 Does the potential speed of change make a difference? It seems to be an important feature of public concerns. Although understanding the basic technology that allows genetic modification to be applied can take many years of detailed study, the eventual application of that knowledge can make quite rapid changes to animals. For example, the ability to modify salmon with growth hormone is underpinned by decades of molecular biology, biochemistry and physiology, but the modification itself led directly to salmon that grow at three times their normal rate. By comparison, conventional breeding has selected for faster growth rate in chickens over the last decades; but this increase has been a more gradual process.
- 74 While speed of technological change is sometimes welcome, our research indicated that the potential speed at which GM could make significant changes to animals causes unease. When combined with the potentially dramatic nature of some changes, particularly the insertion of genetic material from one species of animal or plant to another, concerns for the integrity of animals and for their welfare, and worries about the ability to have control over developments - particularly in relation to animals consumed by people - this concern would seem to be reinforced. This can lead to a desire for slower progress to give more time to monitor the implementation of the technology and possibly correct any adverse effects.

### **WELFARE IMPLICATIONS OF PROCEDURES FOR GENERATING GM AND CLONED ANIMALS**

- 75 As described earlier, development of GM animals by random incorporation of the transgene following microinjection and in vitro culture or both is relatively inefficient. Production of cloned mammals by nuclear transfer leads in some species of animal to a high degree of embryo mortality and foetal abnormality. Some associated procedures with both techniques,

<sup>59</sup> Animal Procedures Committee. *Report on Biotechnology*. 2001. p.15.

such as the use of Caesarean section and other surgery have animal welfare implications. Although some conventional selective breeding also relies on the latter techniques, they are used to a comparatively greater extent in the production of GM and cloned animals. GM and cloning procedures, therefore, can have animal welfare implications. The practical difficulties arising from the unpredictability at present of GM and cloning is also a limiting factor on the usefulness of the techniques.

- 76 Other kinds of breeding can also have welfare implications. For example, another relatively novel technique, the use of implanted embryos in cattle breeding, has led to some cows giving birth to a different breed of calf which is larger than the maternal breed's normal offspring. This has had the effect of increasing the number of caesarean births in cattle, and there are now embryo transfer regulations in place. Also, conventional breeding of livestock in agriculture can involve considerable strains on animals.
- 77 Generation of farm animals by GM or cloning has animal welfare implications. If and when the techniques become more efficient for mammals, the welfare implications of GM and cloning may become less of a concern. For now, the welfare implications of GM and cloning techniques certainly should be taken into account in decision-making, but conventional animal generation can have welfare implications too, which equally should be taken into account.

## **WELFARE IMPLICATIONS OF THE OUTCOMES OF BREEDING PROGRAMMES**

- 78 In terms of the outcome for the animals themselves, the issues raised by conventional selective breeding and GM and cloning programmes bear comparison. Some selective breeding processes have led to major changes in the characteristics of some species of farm animals (and pets).<sup>60</sup> Some of these changes have led to negative consequences for the animals themselves, for example congenital weaknesses in some dog breeds.
- 79 It may also be the case that undesired effects for producers could arise from selective breeding. For example inbreeding might lead to populations becoming vulnerable to disease. DEFRA have in place a programme of research to investigate the causes of the steady decline in the fertility of the dairy and pig herds. The causes of infertility appear to be related to increased growth and performance of livestock but are not understood at present.<sup>61</sup>

60 For example, broiler chickens have been raised with us in evidence as an example. We have heard conflicting reports on the issue of whether these birds suffer significantly painful skeletal defects because they grow so fast. A further study about the prevalence of leg defects has been undertaken by the Royal Veterinary College for the British Poultry Council (BPC) in response to the publication of the Farm Animal Welfare Council (FAWC) *Report on the Welfare of Broiler Chickens*, in 1992. It was the FAWC report that raised awareness of the apparent problem. The BPC report is available on its website ([www.poultry.uk.com](http://www.poultry.uk.com)). FAWC wrote to Government on 16 April 2002 in response to the publication of the BPC study. The FAWC letter can be viewed at [www.fawc.org.uk/whatsnew.htm](http://www.fawc.org.uk/whatsnew.htm). We also welcome the fact that DEFRA is supporting independent research into the factors affecting chicken leg health. We recognise that determining the answers is a complex task.

61 Evidence from DEFRA about DEFRA's livestock research strategy. We understand that around eight percent of all heifers born in the year 2000 were sired by sons or grandsons of a single bull, called Starbuck. There has been discussion about whether the widespread use of artificial insemination (AI) in the dairy herd and the use of a relatively small number of sires to produce many heifers has contributed to the decline in fertility in the dairy herd. DEFRA report that the breeding industry does not see the use of AI and a small number of sires as a problem on the grounds that maternal genes introduced in each generation help guard against in-breeding problems and the selection indices used by producers when selecting a sire are now incorporating factors for a long productive life of the daughter, meaning that traits such as infertility or poor health would not be selected.

- 80 The generation of more productive farm animals illustrates the comparability of conventional and genetic biotechnological techniques. Conventional selective breeding has already produced some animals that grow much faster or are otherwise more productive than their ancestors in previous decades. Marker-assisted breeding could allow the process of selective breeding to take place more quickly. It may also prove possible to use genetic modification to produce higher-yielding animals.
- 81 If marginal welfare problems arise from generating a faster-growing or otherwise more productive farm animal, then these would need to be considered alongside other factors, including economic interests<sup>62</sup> and environmental effects.<sup>63</sup> If the welfare problems were great, then that would presumably override other considerations. The welfare implications for faster-growing farm animals resulting from the application of each of conventional techniques and of GM and cloning are not different in kind. In each case, the benefits and problems would have to be considered.
- 82 Other selective breeding programmes can be beneficial to animals as well as producers: such as breeding in greater disease resistance. For example, work is under way to try to select for resistance to mastitis in dairy cows (GM research is also under way with the same goal). In principle selective breeding could be used to help correct welfare problems in future generations. In order to realise such benefits, however, breeding companies need to make sufficient information available to farmers about benefits not directly related to productivity. Where such benefits - such as health or improved welfare - are economically beneficial, this should be highlighted, so that farmers will be encouraged to take these into consideration. The wider issue of how to reconcile such benefits with the tendency for productivity improvements to drive developments needs to be looked at if greater account is to be taken of benefits to health or welfare which do not offer direct productivity gains.
- 83 In summary, GM, cloning and conventional techniques could lead to either desirable, or undesirable, outcomes in relation to farm animal welfare. Much technological change tends to be detrimental to animal welfare, as its emphasis is on making animals more productive. As noted earlier, cloning in particular needs to be monitored in this regard.

## CONSUMER CHOICE

- 84 Whether or not GM and cloned animals are different, Professor Breakwell's study noted that people want to know what they are eating and to have labelling that enables this.<sup>64</sup> The use of novel products in livestock production, including GM products, may raise issues of consumer choice. If and when GM or cloned farm animals entered commercial production,

<sup>62</sup> It is important to note that the producer interests cannot be considered in a vacuum. There is concern that if unilateral controls on applying technology to animals were introduced in the United Kingdom, that will have the effect, in the present regulatory system, of increasing the import of cheaper products from abroad, quite possibly from animals which have been treated less well than animals reared in the United Kingdom. This issue was the subject of a proposal (Ref G/AG/NG/W/19) in June 2002 from the European Communities to the World Trade Organization's Committee on Agriculture. The proposal suggested ways of ensuring that trade does not undermine efforts in the European Union to improve the protection of the welfare of animals while avoiding trade protectionism. It can be viewed at [www.wto.org](http://www.wto.org)

<sup>63</sup> Relevant environmental factors would include, in so far as productivity improvements are derived from better conversion of feed to bodyweight, more efficient use of feedstuffs, the production of which has implications for land use (this obviously has economic implications too); and any direct impact of the animal on the natural environment.

<sup>64</sup> Breakwell G. *Research in the UK on public attitudes to biotechnology with animals*. March 2001 (available at [www.aebc.gov.uk](http://www.aebc.gov.uk))

there might need to be separate management arrangements, if not regulation, to preserve consumer choice if, as seems likely at present, there is consumer demand for non-GM meat or animal products. This is likely to be a practical difference between GM and conventional farm animals.

## **JUSTIFICATIONS**

- 85 We do not believe that the use of GM and cloning is in itself the key factor for determining public acceptability of particular applications. But GM and cloning give rise to particular concerns for some people so the justification for use of these technologies is even more important than justification of conventional practices involving animals, even if the conventional and genetic biotechnology applications are for the same putative purpose.
- 86 To return to the theoretical examples considered earlier, interference with an animal's normal behaviour at first sight seems intrinsically objectionable and impermissible regardless of the putative benefits. But the precise circumstances and intention behind the production of a fundamentally altered animal need to be carefully considered. While it may widely be considered inherently objectionable to create a new line of GM pigs or GM cows with reduced sentience for agricultural production,<sup>65</sup> the production in the laboratory of a small number of animals which suffer reduced sentience or some other deleterious consequence as an effect of knocking out a gene as part of a research programme intended to improve understanding of gene function, may be considered differently. The debilitation would be a consequence of the knock-out procedure, which was itself being carried out for medical research. The modified animals would not be produced or perpetuated outside the confines of the experimental procedure. Other factors, such as having procedures in place to humanely alleviate any welfare problems that arise for the animals within the procedure, would be relevant.
- 87 GM, cloning and an enhanced understanding of the human genome seem likely to offer a succession of new opportunities for creation of products, such as functional foods, or genetic modification of livestock to have lower fat content or some other perceived health benefit, or 'lifestyle' pharmaceutical products produced using biopharming (or by other means). Some new possibilities of this sort, which may be developed using GM animals in production or testing, would straddle the boundary between medical and other kinds of perceived benefit. Given this, the justification for the use of GM animals in producing them is likely to be quite complex. Future developments in GM and cloning may therefore add new complexity to questions of justification in some aspects of society's relationships with animals. It would be better to consider the questions posed by such possible future developments ahead of time. In Part 2 we recommend that a new strategic advisory body could usefully consider these and similar issues.
- 88 Where the production objectives are considered justifiable, there should also be serious consideration of alternative (non-GM) approaches to achieve the same outcome. This is in line with a study for the European Commission, which recommended that 'when an

<sup>65</sup> This concept finds expression in the EU (1997) protocol on animal welfare (an amendment to the Treaty of Rome), which recognised farm animals as 'sentient beings' and not agricultural products; and the Treaty of Amsterdam (1999), which requires animal sentience and welfare to be recognised in implementing EU legislation.

alternative, non-transgenic, method is at a late stage of development, and is likely to be reasonably and practicably available in the near future, it should be given consideration as a replacement for the proposed use of a transgenic animal method'.<sup>66</sup> The reasoning included the public disquiet over GM animal use, and welfare problems.

## **PART 1.6**

### **THE CONTEXT FOR ANIMALS AND GENETIC BIOTECHNOLOGY**

- 89 The wider contemporary context in which new applications can be expected to arise is a complex one. A number of social and political factors seem to us likely to combine, heightening the urgency of the need for Government to make sure that the regulatory framework is adequate.
- 90 We have noted already that the speed and nature of the changes made possible by GM give rise to significant public concerns and that these have an extra sensitivity when applied to animals. Government will have to engage with these in a context of already intense discussions around the handling of 'science in society' issues,<sup>67</sup> as well as continuing pressures on companies for 'corporate social responsibility'.<sup>68</sup> Beyond this, continuing tensions can be expected between expectations of transparency in regulation and priorities of commercial confidentiality in areas of competitive significance (such as new technologies). More generally, debates around the adequacy and trustworthiness of existing regulatory frameworks can also be expected to continue.
- 91 In short, new GM applications for animals in the UK are likely to arise in a complex and fast-changing context, interacting with other significant social debates. As we have seen from the controversies surrounding GM crops, the challenges for society and in particular for Government can be acute - hence the urgent need to consider the issues in advance in this new domain.

66 Mepham TB *et al*, The use of Transgenic Animals in the European Union. *Alternatives to Laboratory Animals* 26: 21-43 (ECVAM Workshop Report 28). 1998.

67 See, for example, Royal Commission on Environmental Pollution, *Setting Environmental Standards*, October 1998; Parliamentary Office of Science and Technology, *Open Channels: Public dialogue in science and technology*, POST Report No 153, March 2001; and the speech by the Prime Minister to the Royal Society, May 2002.

68 Henderson Global Investors. *Socially Responsible Investment*. 2002.

## **PART 1.7** **CONCLUSIONS**

- 92 As our social research indicated, some people do believe that applying GM and cloning to animals represents a fundamental change in our relationship with animals. On this understanding, GM and cloning require a special sort of justification on ethical and other grounds. Others disagree, seeing GM and cloning as essentially an extension of existing practices relating to animals. Both views, broadly, are represented in the AEBC. We have a range of views, too, about the desirability of applying the technology in agriculture and elsewhere. There are also different views about the significance of emerging trends in the numbers of GM and cloned animals which may be generated for use for various purposes in society, and the value of the purposes for which these animals are being used, in research and elsewhere, or may be used in the future. The different positions are sincerely and strongly held.
- 93 We can agree, however, on a number of potential problems that need to be addressed in the regulatory system for GM and cloned animals, particularly regarding agriculture and the environment. Commercial farming of GM fish or release of GM insects would raise particular environmental concerns which would need to be addressed. Commercialisation of GM or cloned livestock would seem likely at present to give rise to consumer choice issues. The procedures for applying GM and cloning, which are relatively inefficient, can adversely affect animal welfare, as can conventional practices. In terms of the animals produced, in each case there can be negative or positive results for animal welfare. Some potential changes to animals, by whatever means, are fundamentally objectionable. These issues need to be considered and dealt with in the regulatory system. The practical differences between genetic biotechnology and conventional practices are not such as to suggest that GM or cloned animals should be governed separately in every aspect from conventional animals in the regulatory system.
- 94 It makes sense also to consider GM and cloning in the context of society's wider relationships with animals. But questions in relation to GM and cloning are more urgent and sensitive because of the speed and nature of changes to animals made possible by genetic biotechnology, and the issues of concern and in some cases principle, that GM and cloning give rise to for some people. Conventional practices relating to animals should be justifiable and so should GM and cloning. In view of public concerns, we believe that it is right to focus on the use of GM and cloning. Justification for their use needs to be as transparent as possible and the reasons for its use assessable by the public. This is of paramount importance for the regulatory system. The important corollary is that the application of conventional technologies to animals also should be closely scrutinised.





**PART 2**  
**THE REGULATORY**  
**FRAMEWORK**  
**AND OUR**  
**RECOMMENDATIONS**

## **PART 2.1**

### **GUIDING PRINCIPLES FOR REGULATION**

95 We now look at the regulatory system in the light of the considerations in Part 1. A description of the system is at Annex A. Is it capable of dealing with all the relevant factors for decision-making? Is it enforceable and coherent? Is the public likely to have faith in the system as developments continue in the field of animals and biotechnology? Focussing on agriculture and the environment, we now look at the different components of the system: legislation, advisory bodies, and the interpretation and implementation of regulations.

### **PRINCIPLES OF GOOD REGULATION**

96 The Better Regulation Task Force (BRTF) has set out five principles of better regulation, which enjoy wide acceptance. We have sought to look at the present system of legislation, regulatory and advisory bodies in the light of these principles. The BRTF principles are that good regulation should be:

**transparent:** legislation must be easy to understand with aims written in clear and simple language;

**accountable:** people who develop new legislation should answer to Ministers and Parliament, and the public;

**targeted:** legislation should focus on the problems and reduce side effects to a minimum;

**consistent:** new regulation should be consistent with regulation that is already in place and should be predictable; and

**proportionate:** the effect the rules will have on people should be identified and the right balance between risk and cost must be found.<sup>69</sup>

### **GENERAL**

97 In 1999, MORI found that 'The vast majority of the public (97%) believes that it is important that there are rules and regulations in place to control biological developments and scientific research, and as many as 88% believe this is very important.'<sup>70</sup> This, MORI stated, is a high figure for responses in the 'very important' category. People want a robust system, where safety is paramount and there are no or few side effects.

98 The basic historical driver for regulation of activities involving animals in the United Kingdom was to prevent unnecessary suffering to animals used for business or pleasure, a principle which was enshrined in the early part of this century in the Protection of Animals Act 1911.<sup>71</sup>

69 Better Regulation Task Force. *Principles of Good Regulation*. October 2000.

70 MORI. *The Public Consultation on Developments in the Biosciences, December 1998 - April 1999*, May 1999. p.6.

71 Radford M. *Animal Welfare Law in Britain: Regulation and Responsibility*. Oxford 2001. Part B provides an account of the historical background.

As noted in the Banner report,<sup>72</sup> the present regulatory framework is founded on the premise that the uses of animals as livestock or in research or as pets is legitimate, subject to that use being humane.

- 99 The principal relevant factors in relation to society's existing relationships with animals include: benefit to society at large (for example, through medical research); particular economic interests (of producers and consumers); animal welfare; environmental considerations; human health (especially in relation to farm animals produced for human consumption); and the public acceptability of particular developments in society's relationships with animals. The relevance and weight of these different factors will vary according to the nature of the relationship with the animal. The regulatory system should reflect this, but in a targeted way, focusing on preventing problems, including unjustified reductions in animal welfare.

### **GM AND CLONING IN THE REGULATORY SYSTEM**

- 100 At present, all GM and cloned animals in Britain are covered by the Animals (Scientific Procedures) Act 1986 (A(SP)A), because they are considered to be subject to experimental procedures. A(SP)A requires tight regulation of experimentation on these animals, and careful justification of procedures to be carried out on them. There is already, therefore, a requirement to justify the initial generation of individual GM and cloned farm (and other) animals, as part of the general requirement to justify an experimental procedure.
- 101 If and when GM or cloned animals enter production on the farm, however, then they would have been released by the Home Office from the provisions of A(SP)A. They would, like conventional animals, be governed by the same regulatory framework as non-research animals. We believe that it is desirable that GM and cloned animals should be governed post-commercial release by the same legislation as conventional animals. It makes no sense to consider the issues raised by any commercialisation of farm animals (or indeed pets) created using GM and cloning in isolation from the breeding and management of animals by conventional means. To do so would run the risk of incoherence.
- 102 Nonetheless there is a need for adequate monitoring of the long term stability and welfare of cloned and GM farm animals, if and when they enter conventional production. And consumer choice issues will need to be addressed. There will be a need to look very carefully at the environmental impact of any deliberate release of GM fish, and GM insects. We do not believe that GM or cloned farm (or other) animals, however, should as a matter of principle be governed separately in every aspect from conventional animals in the regulatory system on welfare or other grounds.

<sup>72</sup> The Banner Report makes the distinction (paragraphs 2.12-13) between those who advocate 'animal rights' and take the view that non-human animals should be given something close to the same respect that is given to humans; and those who advocate animal welfare, who take the view that the use of animals is acceptable, provided it is humane.

## **PART 2.2**

### **LEGISLATION**

#### **GENERAL ANIMAL WELFARE LEGISLATION**

- 103 The existing foundation piece of legislation for general animal welfare, the Protection of Animals Act 1911 (in Scotland the Protection of Animals (Scotland) Act 1912 and in Northern Ireland the Welfare of Animals Act (Northern Ireland) 1972, which replaced the greater part of the 1911 Act there), applies to GM, cloned and conventional animals, on the farm or elsewhere. We concluded early on that the 1911 Act should be updated, both to take account of genetic biotechnology and more generally. The 1911 Act focuses on a relatively narrow range of practices, some of which, such as the use of dogs for carriage, are no longer contemporary; and the notion of unnecessary suffering requires explication. Practice and attitudes in society have changed since the Act.<sup>73</sup> It also seemed to us desirable to consolidate and simplify the plethora of different pieces of animal welfare legislation, not least to make the legislative framework more intelligible.<sup>74</sup> We accordingly welcomed the launch by DEFRA earlier this year of a review of the 1911 Act and related general animal welfare legislation. For the same reasons, we would welcome a review in Scotland of the 1912 Act, and in Northern Ireland of the 1972 Act.
- 104 Recent animal welfare legislation in Sweden and Germany takes account of the possibility that selection and breeding procedures can result in poor animal welfare. This is not something covered in the 1911 Act, which does not address incremental man-made changes to an animal species which have welfare implications. The provision in the Welfare of Farmed Animals (England) Regulations 2000 that ‘no animals shall be kept for farming purposes unless it can be reasonably expected, on the basis of their genotype or phenotype, that they can be kept without detrimental effect on their health or welfare’ potentially goes some way towards recognising this problem, although how in practice this provision will be given effect remains to be seen. Animals could be produced with a genotype which causes unacceptable welfare problems by GM and cloning or through conventional or marker-assisted breeding. We believe this provision should be borne in mind in the revision of the 1911 Act and of general animal welfare legislation.
- 105 There are other factors that Government will no doubt wish to consider as part of the review. For example, whether there ought to be a positive duty on people to ensure the welfare of animals for which they are responsible, something that is a feature of the Welfare of Farmed Animals (England) Regulations 2000 and the equivalent legislation in Scotland, Wales and Northern Ireland. The extent to which wild animals should be brought within the ambit of the legislation is another issue. The provisions for enforcement of the legislation must also be borne in mind alongside any changes to the Act. Modernising the Act and consolidating associated regulation will not of itself improve animal welfare. The pressures on farmers to increase productivity mean that developments in relation to farm animals tend to be driven

<sup>73</sup> For example, the inclusion in the Breeding Dogs (Welfare) Act 1999 of provisions for a minimum age and limit on the number of litters that a bitch can be expected to bear.

<sup>74</sup> Mike Radford notes in his book *Animal Welfare Law in Britain* (p.299) that while the Act has generally been found adequate in most cases of cruelty that come before the Courts, concern has been expressed from time to time in English and Scottish courts that the language of the Act is confusing and should be brought up to date.

by this factor rather than other considerations, such as animal welfare. This needs to be taken into consideration. And as we discuss in Part 2.4 below, we see a need for an independent review of the effectiveness of the interpretation and enforcement of existing farm animal welfare regulations.

## GM FARM ANIMALS

- 106 We are satisfied that the law relating to farm animals is in principle adequate to meet concerns about GM farm animals which suffer reduced welfare or health problems (through the Welfare of Farmed Animals regulations<sup>75</sup>) or which give rise to unacceptable human health or environmental risks (through the regulations implementing the Deliberate Release Directive<sup>76</sup>). Collectively, the legislation covers those factors that could give rise to concern. We believe, however, that there is a potential gap in the legislation in relation to the case of GM or conventional farm animals, the generation of which leads to what might be judged intrinsically objectionable changes to animals but which does not give rise to clear animal welfare, animal or human health, or environmental concerns. Such changes would include insentient animals or animals with their physical characteristics or normal patterns of behaviour radically and unacceptably altered.
- 107 How might this situation arise? The Animal Procedures Committee has already recommended<sup>77</sup> that if someone were to seek to genetically modify an animal with the intention of substantially altering its nature, no licence should be given. So development of animals which had been changed in intrinsically objectionable ways in the UK with the ultimate object of commercial agricultural production is currently unlikely to be given approval. It is conceivable, however, that such an animal could be created abroad and imported for commercial use into the UK. If such an animal had been produced using genetic modification, it is unclear whether the Deliberate Release Directive, which is concerned with human health and environmental concerns, could be used to prevent release on broader ethical grounds. If the animal did not suffer health or welfare problems, it is not clear whether there is provision in existing UK farm animal or general animal welfare legislation to prevent such animals being used in agriculture in the UK, were it be decided that such use should be prevented. This also would seem to hold true for intrinsically objectionable changes made to an animal by conventional means.
- 108 It seems unlikely that many examples of such animals will be produced, given the effort and expense needed to successfully complete a GM or conventional breeding programme, or that there would be much appetite among producers to keep such animals commercially. Nonetheless, if no such provision was available, and such an animal which had been changed in intrinsically objectionable ways was introduced, this could have a severe adverse effect on public attitudes to other biotechnology developments. This apparent gap should be examined by Government, therefore, in case any such examples arise.

<sup>75</sup> Although we note that these would not apply to GM farm animals in pharming because the animals would not be classed as livestock kept for an agricultural purpose.

<sup>76</sup> See Annex A, paragraph 7.

<sup>77</sup> Animal Procedures Committee. *Report on Biotechnology*. June 2001, recommendation 4. (available at [www.apc.gov.uk](http://www.apc.gov.uk))

109 The regulatory system is perhaps more likely to face less straightforward cases than developments which are clearly intrinsically objectionable. Less clear cut cases, which push at but do not necessarily breach the boundaries of what most people think is acceptable, are difficult to deal with, especially incremental developments. People might be inclined to object to a particular outcome of the breeding of one kind of animal which over time, combined with other changes to the animal, may lead to positive benefits for the animal or society which people would welcome. Alternatively, each step in changing an animal's characteristics for commercial agricultural production (or in some other context) may not itself be clearly objectionable. But the cumulative effect over time may be negative for that sort of animal (for example a shortened natural life span or an increased rate of embryo loss) or for the environment and lead to public concern at the end result. Incremental shifting of ethical boundaries is normal in society, and should be reflected in how the regulatory system works. What is required in relation to animals and biotechnology is the capacity in the regulatory system for independent scrutiny of complex and difficult issues of this sort, especially incremental changes to farm animals, taking a strategic and long-term look at developments, informed by information about public attitudes. We go on to recommend a new strategic body to advise on these issues. The provision of sufficient powers in the regulatory system for intervention in such cases, where intervention is judged necessary, should also be considered.

## **RECOMMENDATION**

GM, CLONED AND CONVENTIONAL ANIMALS SHOULD BE GOVERNED BY THE SAME REGULATIONS WHEREVER POSSIBLE. THE 1911 PROTECTION OF ANIMALS ACT SHOULD BE UPDATED AND OTHER PIECEMEAL ANIMAL WELFARE LEGISLATION CONSOLIDATED. PROVISION WILL BE NEEDED TO PROTECT FARM ANIMALS FROM DEVELOPMENTS WHICH SUBSTANTIALLY ALTER THEIR NATURE IN UNACCEPTABLE WAYS. THE EFFECTIVENESS OF THE INTERPRETATION AND ENFORCEMENT OF EXISTING FARM ANIMAL WELFARE REGULATIONS SHOULD BE REVIEWED.

## **CLONED FARM ANIMALS**

110 There is a potential regulatory gap in relation to cloned farm animals to which the Farm Animal Welfare Council drew attention in their 1998 Report on Cloning.<sup>78</sup> At present, because the cloning is being carried out for scientific and experimental purposes, cloned animals fall within the scope of A(SP)A. But that could change because A(SP)A specifically excludes procedures which are 'recognised veterinary, agricultural or animal husbandry practice'. Thus the cloning of animals, if it became routinely used in agriculture, would fall outside A(SP)A, although aspects of it might be regulated by the professional veterinary societies.

111 Before considering discharge of a GM or cloned animal from A(SP)A, the Home Office would require as a minimum welfare records for two generations of animals living a full lifespan. As we noted above it would also be important to continue to assess if and when cloned animals are commercialised whether there are longer-term welfare or health problems caused by cloning, particularly in a commercial agricultural environment.

<sup>78</sup> FAWC. *Report on the Implications of Cloning for the Welfare of Farmed Livestock*. December 1998.

- 112 We therefore endorse FAWC's recommendation that particular consideration is given to ensuring that cloned agricultural animals continue to enjoy similar protection to research animals, at least until, as FAWC recommended, the point at which the effects of the cloning and any associated genetic manipulation have been scientifically evaluated in the environment of commercial agricultural practice.<sup>79</sup>
- 113 Were cloning of pets or other animals ever to be licensed under A(SP)A and subsequently produced on a commercial scale we believe similar considerations should apply.

## **RECOMMENDATION**

POST-COMMERCIALISATION MONITORING OF GM AND CLONED FARM ANIMALS SHOULD BE PLANNED TO LOOK FOR UNEXPECTED WELFARE OR HEALTH PROBLEMS.

## **ENVIRONMENT, HUMAN HEALTH AND CONSUMER CHOICE**

- 114 The Contained Use and Deliberate Release regulations are concerned variously with protection of human health and safety and protection of the environment in relation to GM organisms. Revised regulations about deliberate release into the environment of GM organisms, giving effect to the European Directive EC/2001/18, have been the subject of a public consultation exercise by DEFRA and the devolved administrations, and are due to come into force in October 2002. We have not come across any specific new issues for these regulations in looking at prospective applications of GM to farm (or other) animals. But we have noted that the present regulations and associated risk assessments are focussed on plants rather than animals. Were greater numbers of GM animals to enter experimental use outside the laboratory, the terms of the regulations and the nature of the risk assessments should be reviewed to check that they adequately cover all the necessary areas.
- 115 In the case of GM fish and GM insects, protection of the environment will be a serious and potentially difficult issue for Government. Environmental concerns about the unintended or intended release of such faster-growing fish into the natural marine environment which might lead to these fish competing with or having unintended negative consequences for native wild species are likely to be very important in considering what sort of regulation may be necessary. There is currently widespread scientific opposition to the commercialisation of GM fish in offshore fish farms. The Royal Society of Canada has called for a moratorium on rearing GM fish in aquatic net pens and for approval for commercial production to be conditional on production taking place in land-locked facilities. The Royal Society has endorsed this. It is difficult to see how the spread of the released GM fish through suitable marine habitats could be controlled. Any negative effects on native fish stocks could have economic consequences also. While there is significant uncertainty about the environmental consequences of the escape of GM fish into the wild and about the containment of the fish, we believe that GM fish should not be raised in offshore aquatic net pens. This judgement could change if the containment was assessed as adequate by the regulatory authorities or the environmental assessment changed.

<sup>79</sup> Ibid, paragraph 47.

- 116 The Advisory Committee on Releases to the Environment has published a case study<sup>80</sup> setting out the factors which they would expect to take into account in making decisions about commercialisation of GM fish in the UK. Our social research suggests that there could well be significant public concern about the consequences of producing faster-growing GM fish. In addition to environmental impact, any health or welfare implications for fish that have been genetically modified to grow faster for the purpose of improved productivity should be assessed.
- 117 Applications to release GM insects into the environment must also be considered very carefully.

### **RECOMMENDATION**

THE COMMERCIAL PRODUCTION OF GM FISH IN OFFSHORE AQUATIC NET PENS SHOULD NOT BE PERMITTED WHILE THERE IS SIGNIFICANT UNCERTAINTY ABOUT THE ENVIRONMENTAL CONSEQUENCES OF THE FISH ESCAPING TO THE WILD AND ABOUT THE CONTAINMENT OF THE FISH IN NET PENS.

- 118 Any environmental issues, including implications for genetic diversity in livestock, of the large-scale commercial (Part 'C') release of GM or cloned animals would also need to be addressed prior to deliberate release. The new directive on deliberate release (EC/2001/18) makes provision for assessment of long-term effects.
- 119 Wider issues of public acceptability and consumer choice would also need to be taken into account if and when commercialisation went ahead if, as seems likely at present, there were a desire on the part of many consumers to be able to choose between GM and non-GM livestock.<sup>81</sup> The system of production would need to prevent accidental cross-breeding on the farm or mixing of products in the supply chain. There would be grounds for concern if there were any possibility of animals used in pharming subsequently breeding with conventional animals, and products inadvertently entering the food chain. However the regulatory framework for contained use of animals - and for any deliberate release applications, of which there have been none to date - has human health as a prime focus for decision-making and in principle it should be possible to avoid such scenarios.

### **RECOMMENDATION**

ARRANGEMENTS SHOULD BE MADE TO MAINTAIN CONSUMER CHOICE ABOUT WHETHER TO PURCHASE MEAT OR OTHER PRODUCTS FROM GM AND CLONED ANIMALS.

80 DoE. *Guidance for Experimental Releases of Genetically Modified Fish*, 1997.

81 In the US, the Food and Drug Administration has asked companies which have produced cloned livestock not to introduce the livestock or products derived from them into the human or animal food chain until the National Academy of Sciences (Board on Agriculture and Natural Resources) has reported on the 'Science-based concerns associated with the products of animal biotechnology'. NAS issued its report in August 2002 as this report went to press. See [www.nas.edu](http://www.nas.edu)

## IMPORT OF GM AND CLONED ANIMALS

- 120 The APC report on biotechnology drew attention to a potential gap in relation to the monitoring of the welfare of GM animals imported into the UK. At present, the use of GM and cloned animals after import is licensed by the Home Office. If such animals were not to be used for a scientific or experimental procedure, however, then they would not be subject to A(SP)A and the welfare monitoring provided for in the Act.
- 121 If the granting of 'Part C' marketing consent<sup>82</sup> in the EU could take into account welfare issues relating to GM animals, and the animals were being imported for commercial use, then there would not be a problem. There is no clear provision in the Deliberate Release Directive to take welfare into account, however, because the Directive is concerned with human health and the environment. We believe that welfare and other relevant considerations such as intrinsically objectionable changes must be dealt with before Part C consent were given, in addition to any environmental and human health considerations.<sup>83</sup> For cloned animals, which are not considered to be covered by the deliberate release regulations, it would be necessary for the cloned farm animal to be identified as such so that a suitable post-commercialisation monitoring regime could be put in place.
- 122 In advance of any GM animal receiving Part C approval, the animal would be required to be suitably contained under the deliberate release regulations. It ought in principle, therefore, to be possible to monitor any such animals, even if they were not being brought in for experimental or other scientific purposes. It would be worth thinking through now how best that might be done in advance of the time when an animal of this kind might be imported for non-experimental purposes but before the animal had been released for commercialisation.
- 123 There is a further question: might such animals be smuggled into the UK? This could cause a problem with regard to consumer choice in relation to animals for human consumption; monitoring of the welfare of cloned animals; and in relation to environmental impact. In practice, it seems unlikely that smuggling is likely to become a major issue in the immediate future, because the vast majority of such animals are being used for experimental purposes, and it is unlikely that the establishments using GM animals for experimental purposes would risk failing to obtain a Home Office licence for the acquisition and use of the imported animals, just as is required for animals generated in the UK. It also seems unlikely at the present time that the relatively small number of high-value GM or cloned animals used in biopharming or agriculture will be the subject of smuggling: the animals are too valuable to their producers. This is just as well, because it is hard to imagine how the regulatory system would deal with trying to identify a smuggled GM or cloned animal at a port of entry. One could not assess by inspection whether a pig, let alone an embryo, had been genetically modified.
- 124 When importing an animal from outside the EU, it is not possible to know that it has been genetically modified unless the exporting country informs the relevant EU Border Inspection Post responsible for examining imported animals (which could be in any Member State).

<sup>82</sup> Under the deliberate release regulations.

<sup>83</sup> The provisions in the recent Farm Animal Welfare Regulations that no animals shall be kept for farming purposes unless it can be reasonably expected, on the basis of their genotype or phenotype, that they can be kept without detrimental effect on their health or welfare, should provide an additional safeguard for farm animals in addition to any consideration of welfare prior to deliberate release. That safeguard would be extended to other animals if similar provisions were made in revised general animal welfare legislation.

- Should the UK be the importing country, the enforcing agency would be the State Veterinary Service, whose principal concern in relation to imports at present is examination of animal health. There is at present no requirement for the export certificate to state whether animals or embryos have been genetically modified or cloned.
- 125 One of the more likely methods of importing GM or cloned breeding material would be through imported animal semen, ova or embryos. Current regulations<sup>84</sup> on the import of semen, ova and embryos implement EU animal health requirements and do not specifically provide for controls on GM or cloned reproductive material.
- 126 If cloned or GM animals became more widespread an international system for tracking them would seem to be the only practicable regime. The Cartagena Protocol on Biosafety provides an international framework to require exporters of GM organisms to seek prior consent from importing countries. In the case of farm animals for human consumption EU labelling and traceability requirements would be expected to provide the necessary safeguards. The Protocol and in consequence the proposal on Regulation to implement those parts of it not yet covered by existing European Community law<sup>85</sup> are considered to encompass GM semen, ova or embryos.<sup>86</sup> Thought should be given to tracking cloned animals and embryos also. Cloning does not fall within the scope of the Protocol.
- 127 No international system, however, will be able to guard completely against the adventitious or deliberate spreading of some GM animals, particularly fish or insects, released into the environment in one part of the world and brought into the UK. This has occurred many times through history with conventional foreign species which have been introduced into a different eco-system. The fact that some fish move around the world's oceans means that regulation in this area is a trans-national issue.
- 128 The arrangements envisaged in the Cartagena Protocol should be developed sufficiently ahead of time before any production and trade in GM or cloned animals becomes widespread. Developed countries will need to continue to support the building of capacity in developing countries relating to questions of deliberate release into the environment of GM organisms and to monitor their production and export if and when that occurs.

## **RECOMMENDATION**

THE INTERNATIONAL MOVEMENT OF GM AND CLONED ANIMALS AND REPRODUCTIVE MATERIAL SHOULD BE MONITORED.

<sup>84</sup> In England these are the Animals and Animal Products (Import and Export)(England and Wales) Regulations 2000 and the Products of Animal Origin (Third Country Imports)(England) Regulations 2002.

<sup>85</sup> DEFRA launched a consultation on the implementation proposal in July 2002.

<sup>86</sup> Sperm, ova and embryos are not explicitly mentioned in the definitions (Article 3, Use of Terms) in the Protocol but would seem to be covered by the term 'Living Organism' in the Protocol, which is defined as 'any biological entity capable of transferring or replicating genetic material'. 'Living Modified Organisms', the subject of the Protocol's provisions for international monitoring, would therefore cover GM sperm, ova and embryos.

## RESEARCH ANIMALS

- 129 The vast majority of animals under the aegis of the Animals (Scientific Procedures) Act 1986 (A(SP)A) are used for non-agricultural research and do not raise particular environmental concerns because they are kept in laboratories. We have noted that the generation of all new GM and cloned animals would require a licence under the Act, so there is in principle scope for effective regulatory oversight of the production in research of new GM and cloned farm animals. But we have not looked in detail at the quality of the decision-making process under A(SP)A and within the Animal Procedures Committee (APC), the statutory advisory body set up under the Act, as this falls outside our remit. We note that the House of Lords Select Committee on Animals in Scientific Procedures, on the other hand, has recently published a report on the use of animals in scientific research which gave a general endorsement of the operation of A(SP)A and concluded that the UK should not aim for the tightest regulation but for the best regulation, properly enforced.<sup>87</sup>
- 130 The overall number of GM animals used in research has been raised as a concern in some quarters.<sup>88</sup> In recent years the total number of animals used in research has tended to decline. But the number of GM animals is now rising steeply and is set to reverse the overall decline in numbers, and the recent House of Lords inquiry noted these trends.<sup>89</sup> The legislation requires that the numbers of animals used in individual procedures should be minimised. It has no concern, however, with the overall effect of new technologies on the numbers of animals used in research. The new strategic advisory body we propose below could consider this issue.

## PART 2.3 ADVISORY BODIES

### FARM ANIMALS

- 131 The Farm Animal Welfare Council (FAWC) is the independent advisory body concerned with farm animal welfare in England, Scotland and Wales. It is charged with keeping under review the welfare of farm animals on agricultural land, at market, in transit and at the place of slaughter; and to advise the Government of any legislative or other changes that may be

<sup>87</sup> The House of Lords Select Committee on Animals in Scientific Procedures reported on 16 July 2002. It took the view that it is morally acceptable for human beings to use other animals, but that it is morally wrong to cause them unnecessary or avoidable suffering. It concluded that there is at present a continued need for animal experiments both in applied research and in research aimed purely at extending knowledge; toxicological testing in animals is at present essential for medical practice and the protection of consumers and the environment, as it often provides information that is not currently available from other sources; the UK should not strive for the tightest regulation but for the best regulation, properly enforced; the availability to the public of regularly updated, good quality information on what animal experiments are done and why, is vital to create an atmosphere in which the issue of animal experimentation can be discussed productively; there is scope for the scientific community to give a higher priority to the development of non-animal methods, and more consideration could be given to the pursuit of the three Rs - reduction, refinement and replacement; and the development of scientifically valid non-animal systems of research and testing is important, not just to improve animal welfare, but to provide substantial benefits for human health. House of Lords. *Select Committee on Animals in Scientific Procedures*. July 2002.

<sup>88</sup> See for example, Rutovitz J and Mayer S, *Genetically Modified and Cloned Animals. All in a Good Cause?*, Genewatch UK. April 2002.

<sup>89</sup> House of Lords. *Select Committee on Animals in Scientific Procedures*. July 2002.

necessary. The evidence we have heard from industry and Government suggests that FAWC's good links to the agricultural industry are useful. They ensure that the economic requirements of UK producers are taken into account in drawing up their advice, which is necessary if recommendations are to be realistic.

- 132 We have been concerned to learn that Government has not always responded quickly (or sometimes at all) to FAWC's reports. FAWC only recently received responses to two reports it made in 1998, on Broiler Breeders and Cloning respectively. They have received only partial responses to the Reports on Laying Hens (1997), Dairy Cattle (1997) and Enforcement of Animal Welfare Legislation (1999). To add to the list, FAWC has produced a further two reports in 2001 and one so far in 2002. The delays in responding to a high number of reports would appear to be partly due to resource constraints in the relevant division of MAFF (now DEFRA) and partly the complexity of some of the issues FAWC has raised. DEFRA officials have told us that they are committed to improving the response rate and the production of responses to the two outstanding reports from 1998 provides some evidence of this. This is important. The failure of Government even to respond to the recommendations of one of its advisory bodies will not inspire public confidence in the regulatory system. This was a point that was made to us strongly by members of our public reference group.
- 133 In addition to improving the response rate to FAWC reports, Government<sup>90</sup> might usefully send out a public signal about the importance it attaches to receiving, and giving proper consideration to, independent advice about farm animal welfare. It could do so by making FAWC a statutory body. Making FAWC statutory in itself would not improve farm animal welfare, nor should it change the functioning of the Council. FAWC's terms of reference should stay the same, as should its present freedom to set its own priorities for its workplan. Rather, it would be a symbolic act, as part of a bolstering of the priority given to farm animal welfare.
- 134 Some of the respondents we consulted from non-governmental animal welfare organisations expressed concern that FAWC did not have sufficient teeth. FAWC is an advisory, not a regulatory body. It is simply not in a position to undertake the huge operational job of enforcing farm animal welfare standards, nor could it be. That is the responsibility of others. We believe that there is a case for reviewing the enforcement of existing farm animal legislation, and we recommend this in Part 2.4 below.
- 135 Livestock farming has environmental implications. The Environment Agency, the Scottish Environmental Protection Agency, the Sustainable Development Commission, the Royal Commission on Environmental Pollution, English Nature, the Countryside Council for Wales, Scottish Natural Heritage and the Joint Nature Conservation Committee variously regulate, advise and work with rural communities in relation to the natural environment, including the impact of agricultural practices. Consideration of any environmental impacts of applications of GM and cloning to farm animals is outside FAWC's remit. We see the benefit in environmental advisory bodies concentrating on the environment and FAWC retaining its focus on farm animal welfare in the context of a viable livestock industry. But we also see benefit in having a forum where the environmental, industry and welfare interests can be considered together as and when necessary: one reason for our recommendation below for a new strategic advisory body.

<sup>90</sup> That is, the UK Government, Scottish Executive and Welsh Assembly Government.

- 136 The recommendation of the Policy Commission on the Future of Farming and Food for England that the present Red Tractor assurance scheme should be extended to cover environmental standards and that welfare standards should be reviewed<sup>91</sup> is relevant here. The Food Standards Agency is undertaking a review of food and farm assurance schemes.<sup>92</sup> These schemes are designed to assure consumers that food has been produced in accordance with certain standards. FAWC have made an interim report on such schemes.<sup>93</sup> As the Policy Commission said, a revamped scheme of this sort could offer farmers recognition of good practice in relation to food safety, animal welfare, hygiene, agriculture and the environment. The system, adopted in Sweden, which ties incentive payments to the livestock industries for improved welfare, bears examination in this context, and we welcome FAWC's intention to look at this further.
- 137 The devolved administrations have undertaken different studies into the future of agriculture in their respective areas. We hope that they will take into account similar considerations. If the UK Government accept the Policy Commission's recommendation we would expect FAWC, working closely with industry, environmental regulatory bodies and the Food Standards Agency, to give independent advice on a revised baseline farm assurance scheme. It would also be possible for FAWC to work on these issues with comparable bodies in Scotland and Wales.<sup>94</sup>

## RELEASE INTO THE ENVIRONMENT OF GM ANIMALS

- 138 The Advisory Committee on Releases to the Environment (ACRE) has already considered the environmental implications of questions of release of GM fish.<sup>95</sup> In a statement about GM animals made to the AEBC in July 2001, ACRE reported that it strives to be proactive in thinking about future release applications. ACRE has not had to deal to date with applications for the deliberate release of GM animals. If and when it had to do so, it would seek an expert opinion where it did not have sufficient expertise among the present Committee membership and look to have its membership adjusted as required if there were an increasing number of applications for GM animal release. We welcome all this. We believe that this is important as part of the decision-making process and that ACRE is best placed to assess the potential environmental effects of GM animal release. We would expect Government to take into account ACRE's advice on the environmental impact of the deliberate release of a GM farm (or other) animal.

91 Policy Commission on the Future of Farming and Food. *Farming and Food: A Sustainable Future*. January 2002, p.40.

92 Food Standards Agency Press Release. *Agency to review food assurance schemes*. 7 November 2001 ([www.foodstandards.gov.uk/press\\_releases/uk\\_press/2001/pr011108.htm](http://www.foodstandards.gov.uk/press_releases/uk_press/2001/pr011108.htm))

93 FAWC. *Interim Report on the Animal Welfare Implications of Farm Assurance Schemes*. August 2001.

94 Northern Ireland is considering similar issues but FAWC's remit does not extend there. This, we understand, is for historical reasons (FAWC's forerunner body only covered Great Britain). We understand the devolved administration in Northern Ireland will be examining whether the new Farm Animal Welfare Advisory Council in the Republic of Ireland could fulfil this advisory role in Northern Ireland. If not, Northern Ireland Executive Ministers might consider whether FAWC's remit should be extended to Northern Ireland.

95 DoE. *Guidance for Experimental Releases of Genetically Modified Fish*. 1997.

## OTHER ADVISORY BODIES

139 In line with our terms of reference, we have concentrated on issues for agriculture and the environment. But because developments in research may have implications for agriculture, and because possible developments in GM and cloning with farm animals need to be viewed in the context of developments with pets, sporting and other animals, we also cover briefly below some issues in relation to other animal advisory bodies.

## PETS

140 The application of GM and cloning to pets ('companion animals') is outside the terms of reference of the AEBC. But selective breeding has been applied to both pets and agricultural animals and so has GM and cloning. Moreover, the lucrative pet market could drive research priorities in genetic biotechnology, with wider implications (see Part 1.3). By way of illustration, some aspects of human in vitro fertilisation research, such as applying the technology to much older women, have been driven by private funding.

141 Given our remit, our conclusions in this area are accordingly tentative. We believe first that it is important that the implications of prospective applications of GM and cloning to pets are assessed strategically alongside developments in research and agriculture. We also believe that serious consideration should be given to affording the welfare of pets - with which society has a different relationship from that with farm animals - the same sort of independent consideration as FAWC is set up to do in relation to farm animals. We believe there is a good case for Government making the Companion Animal Welfare Council (CAWC) an official body, reporting to Government and being funded by Government.<sup>96</sup> We suggest that CAWC should remain separate from FAWC because the interests, including commercial and other issues connected with pets, are quite different from those concerning farm animals, particularly in relation to the economics of food production. As CAWC is at a much earlier stage of operation than FAWC,<sup>97</sup> we suggest that CAWC need not be made a statutory body at present. As CAWC develops, it could become appropriate to change this.

## ANIMALS IN RESEARCH

142 For the reasons set out earlier, we have not explored the way in which the law is interpreted and applied, only the extent to which it could in principle cover issues relating to biotechnology in agriculture and the environment. It is clear, however, that the way in which the law in relation to research is interpreted and applied will be key to the public acceptability, or otherwise, of the use of biotechnology in non-research environments. The Animal Procedures Committee (APC) will therefore need to command public confidence in the approach it adopts.<sup>98</sup> This means among other things that it must be in touch with public sensibilities to animal uses and sensitive to them in its deliberations. It will also need to be as transparent and open as possible in its workings.

<sup>96</sup> At present CAWC is not an official body and receives no funding from Government.

<sup>97</sup> CAWC was set up in 1999.

<sup>98</sup> The APC reported in 2001 on genetic biotechnology: *Report on Biotechnology*, July 2001. Available at [www.apc.gov.uk](http://www.apc.gov.uk)

143 The APC has considered recently the question of greater openness<sup>99</sup> about animal experimental procedures, concluding that ‘total openness, as supported by a number of individuals’ and animal protection organisations’ responses [to an APC consultation] is not practical, chiefly because of concerns in relation to personal security, but also because of issues about commercial confidentiality.’ The APC’s ‘aim, however, has been to recommend measures which will lead to the greatest degree of openness compatible with those concerns.’ This is a difficult area, and inevitable tensions between transparency and commercial confidentiality make it a matter of potential sensitivity, but we would add our encouragement to the Home Office and APC to pursue this goal, because the data we have on public attitudes to GM and cloning and the regulatory system more generally suggests the importance of making transparent the purposes of specific applications of the technology to animals. Our social research suggests that people feel somewhat in the dark in relation to what is going on in research using biotechnology and animals and this will affect their attitudes to biotechnology and animals more generally. The recent House of Lords Select Committee report concluded that it is vital that regularly updated, good quality information on what animal experiments are done and why is made available to the public; and made recommendations designed to improve the quantity and quality of the available information.<sup>100</sup>

## SPORTING ANIMALS

144 The breeding of racehorses and greyhounds is subject to rules set by industry bodies. Retired sporting animals might be classed as companion animals but careful thought would be needed about the extent to which sporting animals should be included in the advisory framework for animals. Sporting animals do not fall obviously within our remit and we have accordingly not considered this area in further detail.<sup>101</sup>

## USE OF NOVEL PRODUCTS ON ANIMALS

145 The Animal Procedures Committee’s report on biotechnology drew attention to a concern about the implications for animal welfare of the application of products derived from genetically modified organisms (GMOs) to animals.<sup>102</sup> If these substances were administered to animals for scientific or other experimental purposes A(SP)A would apply, but not if they were administered as part of recognised veterinary practice or husbandry procedures. An example of this is recombinant bovine somatotrophin (BST), which is designed to promote increased milk yield in cows.<sup>103</sup> BST has been banned in the EU on human health and animal welfare grounds, although its use is widespread in the US. A similar technology is being developed aimed at increasing piglets’ weight at two months by 40 percent as a result of injecting them at three weeks of age with ‘a package of DNA that boosts the production of the pig’s natural growth hormone’.<sup>104</sup>

99 Animal Procedures Committee. *Report on Openness*. August 2001.

100 House of Lords Select Committee on Animals in Scientific Procedures, *Report* July 2002, chapter 9.

101 The Zoos Forum provides advice to Government on zoo animals.

102 Animal Procedures Committee. *Report on Biotechnology*, June 2001, paragraph 151.

103 It should be noted that non-GM BST can also be applied to cows, but it is only through genetic biotechnology that anything like sufficient quantities of BST can be produced for application on a commercial scale.

104 Coghlan A, *New Scientist*, 18 December 1999.

146 Approval of novel veterinary products, including all GM-derived products, on farm animals is undertaken at EU level. The example of BST suggests that the EU is likely to take into account welfare considerations as well as food safety in coming to conclusions about the use of these products. The Veterinary Products Committee (VPC) is the advisory body in the UK that deals with welfare issues in this context. It is important that animal welfare, as well as human and animal health and environmental considerations continue to be taken into account in assessing novel products for approval and that the VPC continues to monitor that this happens. Government will also wish to consider whether novel products are likely to raise issues of consumer choice or other concerns with regard to animal products which would need to be addressed.

### **A NEW STRATEGIC ADVISORY BODY**

147 We have concluded that a new strategic advisory body is needed. It has an important role to play in developing thinking on GM and cloned animals ahead of possible commercialisation. We have focussed on agriculture and the environment in this report, as this is at the core of our remit. Other bodies have also recommended, from within their own remits, a body with a broad scope, to deal with aspects of society's relationships with animals. The Banner report called for a new advisory standing committee to be created to take responsibility for broad ethical questions relating to current and future developments in the use of animals. FAWC recommended the establishment of a National Standing Committee to oversee the development of cloning technology.<sup>105</sup> We would ask Government to take a wide view and to consider our proposal alongside these other proposals.

148 We see a real need for a strategic consideration of the possible applications of biotechnology to farm animals. But we believe it makes sense to consider issues around GM and cloned farm animals in the context of the application of genetic biotechnology to other animals: some biotechnology applications, such as cloning, already are or could in principle be applied to farm animals or pets or animals in research. In order to effectively consider GM and cloned animals in agriculture, the body would need to look at developments in other aspects of society's relationships with animals. It also should view these developments in the context of conventional practices relating to farm animals, taking account of the strategic direction of livestock farming. Farm animals should be considered in their wider context, rather than entirely separately, not least because as the technology develops there is likely to be a blurring of currently distinct areas, for example farming, biopharming and health.

149 The new advisory body would be a forum for taking a holistic view of the implications of developments common to the different kinds of animals, both in relation to GM and cloning and other developments, particularly where the issues are complex and likely to be of interest to the public and stakeholders. The new body should ensure that GM and cloning applications, particularly those in agriculture and the environment, are spotlighted, to deal with the public concerns which already exist and to anticipate future ones. We believe it is vital to anticipate the likely trajectory of public concerns about the application of GM and cloning and to take a strategic look at the key conditions necessary for the public to have

105 MAFF, *Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals*, 1995; and FAWC, *Report on the Implications of Cloning for the Welfare of Farmed Livestock*. December 1998.

confidence in the system. The new body should seek to chart possible ways through these potentially difficult issues, taking a strategic look at decision-making in relation to applying GM and cloning to farm and other animals.

## Remit

150 The remit of the new strategic advisory body could include the following:

- to provide strategic advice to Government about issues raised by genetic biotechnology and developments in conventional practices relating to farm animals, taking account of the different relationships society has with animals, all relevant factors, ethical considerations, and the key conditions of public acceptability around how animals are treated;
- to review, understand and be informed by the implications of issues affecting farm animals (what happens in sectors beyond farm animals will have ramifications for animals in agriculture, and for the way biotechnology in agriculture is received);
- to develop a strategic view about how society relates to and uses farm animals;
- to review the extent to which Government is responding to independent advice on the issues;
- to seek to lead the debate in the United Kingdom, within the EU and internationally;
- to greatly improve public understanding of the uses and treatment of animals, in particular spotlighting developments in genetic biotechnology relevant to agriculture;
- to facilitate as appropriate proper co-ordination and exchange of best practice between the advisory and enforcement organisations relating to farm and research animals and pets;<sup>106</sup>
- to look ahead at scientific and commercial developments, and their implications, maintaining an international perspective; and
- to enhance engagement with the public, drawing on existing best practice<sup>107</sup> and developing innovative approaches.

## Work topics

151 Areas the body could look at include:

- the review of the 1911 Act and related legislation;
- the underlying social issues relating to our relationships with animals;
- the implications for agriculture and for industries employing animal research of developments in the EU and overseas and internationally;
- spotting any gaps in social and scientific research in relation to society's relationships with animals; and
- periodically, the processes of decision-making in relation to animals, particularly with regard to GM and cloned animals, to assist consistency of approach as appropriate.

<sup>106</sup> It has been suggested to us, for example, that there could be value in greater sharing of information between the Health and Safety Executive and the Home Office on welfare considerations relating to contained use animals.

<sup>107</sup> See the AEBC's advice (April 2001) to Government on how effectively to promote a public debate about the possible commercialisation of GM crops for a discussion of some of the techniques of public engagement being employed in the UK and elsewhere. See also *Open channels: public dialogue in science and technology*, Parliamentary Office of Science and Technology, Report No 153, March 2001.

- 152 The new body could also examine how effectively existing regulation was being interpreted and enforced in relation to animals. We see a need for such a review in agriculture (see Part 2.4 below). It could also review how Government and industry respond to the existing advisory bodies' recommendations. It might also consider the implications of trends in the overall numbers of GM and cloned animals; and the likely environmental impacts of GM animals.
- 153 In addition, as noted earlier, consumer choice seems likely at present to be an issue if and when GM and cloned livestock enter commercial production. The use of novel products in livestock production, including GM products, may also raise issues of consumer choice. Consequently, thought needs to be given now to what arrangements might need to be put in place to deal with this. This could be an area for the new strategic body to consider.

### **Options for a new body**

- 154 We considered a number of possible options for a new strategic body to meet these requirements.
- 155 Mistrust of Government as a regulator in this area came out strongly in our public reference group workshops, and also in the social research we commissioned. To deal with this, we believe that the new strategic body should be, and be seen to be, independent from Government. Accordingly, a committee of Government officials from different departments would not fit the bill. A purely co-ordinating body of the three existing advisory chairs would not be sufficient for the larger job that there is to do in building public confidence in decision-making on GM and cloned animals. That said, it is important that those working in each regulatory and advisory area are sufficiently well informed of relevant developments in the other areas. The new body would be likely to facilitate the exchange of best practice, building on the present regular exchanges between the chairs of the existing advisory bodies in the Animal Welfare Advisory Bodies forum.
- 156 We believe that the new strategic advisory body should be set up by statute as a standing body. Statutory, because this will be symbolic of Government's intention to take issues around GM and cloned animals seriously and that it plans to pay careful attention to the new body's advice. Standing, because we are at the relatively early stages of the application of genetic biotechnology to farm and other animals and ongoing thinking and monitoring will be required.
- 157 We rejected the option of creating an overarching regulatory body with oversight of other regulators because that would be relatively disproportionate, untargeted and probably impracticable. It would not clearly add value. We do not believe that a new advisory body would lead to an unwarranted regulatory burden.
- 158 The existing advisory bodies would continue to report on the areas within their terms of reference. But they could turn to the new strategic body in considering some of these broader and more strategic issues. If the chairs of the existing bodies were members of the new strategic body we believe that that would also help ensure that duplication was avoided. Our public reference group at its second workshop highlighted the main dangers facing the new body as excessive bureaucracy at one end and having too wide a remit at the other. We agree that the new body must avoid both, and this arrangement should help achieve that.

### Views of our public reference group

159 We tested out our conclusion that a new strategic body should be advisory rather than regulatory with our public reference group. None of the public reference group members at their third workshop, at which AEBC sub-group members presented this conclusion, initially shared our view that the body should be advisory, but wanted instead a single body that would have powers independent from Government to regulate biotechnology applications to animals. The report of the workshop notes that:

‘the most common, and most vehemently expressed concern was that the strategic body as proposed by the AEBC would not have regulatory powers, but would be ‘yet another’ advisory body...A purely advisory body, as they saw it, would have a ‘lack of teeth’. This perception seems to come from an ingrained assumption that advisory public bodies are simply layers of bureaucracy and government pawns, rather than independent organisations having important effects. Power is equated, in this assumption, with ‘teeth’. Participants wanted to know the exact status of existing bodies, and some idea of how much they are actually listened to. Some participants in one group compared the strategic body to OFSTED. Their ideal body would be feared, as OFSTED is, by those who came under its umbrella.’<sup>108</sup>

- 160 Reference group members at the third workshop were also concerned that a new body should be resourced adequately, and wondered whether funding would be made available to implement its recommendations. They were further concerned that EU and WTO rules might prevent its recommendations being implemented.
- 161 This feedback supports the idea that we should look to the new strategic body to help the UK to take the lead in international fora in relation to developments relating to animals. It should take an international perspective and might usefully seek to build links with European counterparts and seek to lead the debate in the UK and in the EU about appropriate ways forward, recognising that it is of course always a matter for Ministers to decide ultimately whether and how to implement recommendations from advisory bodies.
- 162 In the course of the dialogue AEBC members had with the reference group, we explained why we did not believe that a strategic *regulatory* body could be justified at this stage as proportionate. To add a regulatory body on top of or to replace the existing structures would be duplicatory and certainly unwieldy. We also said that we were nonetheless convinced of the need to have a new strategic body to consider issues relating to animals, particularly relating to GM and cloning - and that there was a much better chance of gaining agreement in Government and also among some influential stakeholders in this debate if our recommendation was for an advisory and not a regulatory body. The report from the workshop notes that ‘these arguments were encouraging for many participants, and caused their scepticism about creating an advisory body to subside.’ However, the general view among participants was that the proof of the pudding will be in the eating and nothing will convince them to give whole-hearted approval until then.<sup>109</sup>

<sup>108</sup> MORI. *Public Reference Group Study: Public Reactions to AEBC Proposed Strategic Body*. February 2002, p.13.

<sup>109</sup> *Ibid*, p.13, 17.

163 Despite the strongly expressed views of our reference group in favour of a new regulatory body, we remain of the view that a new regulatory body would be unwieldy. We take the concerns expressed by our reference group seriously. Their reaction strongly suggests that it is vital that Government takes seriously and is seen to take seriously the recommendations from any new and existing advisory bodies. Again, from the report of the workshop:

‘The role of government was the second most common cause for questioning and concern. In particular, this focussed on a belief that governments keep information behind closed doors or disclose snippets (but only snippets) selectively as and when it suits their purposes. In addition, participants feared the body would become a government mouthpiece. Their approach to this was a *‘we’ll believe it when we see it’* approach. Around half took on board the argument that placing the new body between existing bodies and the government would simply add another new layer of bureaucracy, and acknowledged that specialist bodies must be able to communicate directly with government. However, the distrust in governments’ reliability to be free and open, that was expressed so vociferously in both July and October, was clearly borne out here in participants’ quick condemnation of the prominence of government in the proposed picture.’<sup>110</sup>

164 If any new advisory body’s recommendations - and those of existing advisory bodies - are not taken seriously by Government, we believe that pressure may grow for new regulatory structures in relation to GM and cloning.

### **Membership**

165 The precise membership of the new advisory body would be a matter for Ministers in the usual way, but we believe that it should not be too large; should have a respected independent chair; have as members the three chairs of the APC, FAWC and CAWC; and have among its members or within its easy reach people with a set of skills and experience drawn from science, the biotechnology industry, veterinary and human medicine, food and farming industries, sporting and other non-agricultural animals, moral philosophy, law, economics, environment, social science, consumer interests and non-governmental organisations. The membership must give the public confidence that the body will take an independent approach and that it can look across the whole area of society’s relationships with animals.

166 Our reference group members gave considerable thought at their second workshop to membership of a new body. The kinds of people they thought should be involved are included in this list. The reference group thought it equally important that both technical experts and non-scientists were included on a new body. The reference group, at both its second and third workshops, was less certain about direct lay membership on the new body. But they were very clear that the body needed to ensure it was aware of and dealing with public views, and in particular minority views. Reference group members also wanted it to be accountable, and in their second workshop said that the body’s remit should fall within ethical parameters set by Parliament. One of the key priorities for reference group members at their second workshop was to be able to trust the members of the relevant advisory bodies to act in a responsible and unbiased way.

<sup>110</sup> Ibid, p. 14.

- 167 The new strategic body itself should operate in an open and transparent way. We would expect Government to fund its operation. The AEBC itself could not undertake the functions of the new body because first, the new body would need to be a standing body; second, we support the principle of holistic consideration - so the new body would look at issues outside the AEBC's remit; and third, the new body would need a different membership to the AEBC.

### **RECOMMENDATION**

A NEW STRATEGIC ADVISORY BODY SHOULD BE SET UP BY STATUTE TO EXAMINE ISSUES RAISED BY THE USE OF GENETIC BIOTECHNOLOGY ON FARM ANIMALS IN THE CONTEXT OF ITS USE ON OTHER ANIMALS AND CURRENT LIVESTOCK FARMING PRACTICES.

### **Public engagement**

- 168 We would again emphasise the requirement for a stronger connection between the public and the advisory and regulatory process. In the light of indications about public attitudes, dialogue will be necessary if the same problems encountered over GM crops are to be avoided and in order to determine what are the key necessary conditions for public acceptance of prospective developments. Our reference group, at its second workshop, set out some way that the public might be enthused to take part in dialogue in this area.<sup>111</sup> Throughout, reference group members said they would welcome a body that sought to make available more and better, jargon free information about developments relating to animals. The need to provide more information and to seek to build public confidence in the regulatory system was a point made to us by a range of stakeholders, including both non-governmental organisations and representatives of industry; as well as in our reference group workshops and in the Macnaghten report.
- 169 Some group members did not necessarily want much more information: knowing that there was this transparency, combined with having trustworthy people involved in the advisory regime, would be sufficient. This chimes with experience in public engagement elsewhere: people differ in what they need and want by way of information and dialogue. Most people are not seeking active involvement all the time. The evidence from our reference group suggests that what they want is a system that they can trust and that is open to dialogue, with information available for those who want it. We believe that it is important that the advisory bodies have sufficient resources to undertake public engagement activities.

### **RECOMMENDATION**

NEW METHODS AND FUNDING SHOULD BE USED TO ENGAGE THE PUBLIC IN DECISIONS ABOUT GENETIC BIOTECHNOLOGY.

<sup>111</sup> MORI. *Public Reference Group Study Phase 2*. October 2001, pp. 20-21 (available at [www.aebc.gov.uk](http://www.aebc.gov.uk))

170 A new strategic body would wish to draw on existing expertise in providing advice on different areas of society's relationships with animals. It will no doubt consider the different ways in which past and present bodies which have provided advice in these areas have approached their task, particularly regarding emerging biotechnologies. These include in particular the Banner Committee;<sup>112</sup> the Farm Animal Welfare Council;<sup>113</sup> the use of an Ethical Matrix to evaluate the issues involved, employed, for example, in recent Food Ethics Council reports,<sup>114</sup> and the work of the Animal Procedures Committee.<sup>115</sup>

## **PART 2.4**

### **INTERPRETATION AND IMPLEMENTATION**

171 Agreed standards relating to animals can be enshrined in regulation but the regulatory provisions must be interpreted and implemented effectively. In areas of public concern, this must be seen to be effective. On the question of interpretation, we have flagged up earlier our concern about how and to what extent the provision in the Welfare of Farmed Animals Regulations, that only animals with a suitable phenotype and genotype should be commercially farmed, is to be applied in practice.

172 We have not ourselves reviewed in depth the implementation of existing regulation. In looking at the adequacy of the existing regulatory system to deal with any future commercialisation of GM and cloned animals, we heard evidence that suggested that the interpretation and enforcement of present regulation in relation to farm animals is insufficiently robust. We have noted the submission made by the Farm Animal Welfare Council to the Policy Commission on the Future of Food and Farming, which stated that 'current levels of welfare surveillance are inadequate to ensure problems and trends will be reliably noticed and appropriate enforcement action taken...Likewise enforcement of current welfare regulations is both inconsistent and inadequate.'<sup>116</sup> We believe that there needs to be effective scrutiny of how well existing welfare legislation is being implemented in relation to farm animals.

112 The Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals ('Banner Committee') in its report set out three principles explicating the concept of the humane use of animals: harms of a certain degree and kind ought under no circumstances to be inflicted on an animal; any harm to an animal, even if not absolutely impermissible, nonetheless requires justification and must be outweighed by the good which is realistically sought in so treating it; and any harm which is justified by the second principle ought, however, to be minimized as far as is reasonably possible.

113 The Farm Animal Welfare Council (FAWC) takes into account five freedoms in its consideration of farm animal welfare. FAWC states that 'these freedoms define ideal states rather than standards for acceptable welfare. They form a logical and comprehensive framework for analysis of welfare within any system together with the steps and compromises necessary to safeguard and improve welfare within the proper constraints of an effective livestock industry.' The five freedoms are freedom from hunger and thirst; freedom from discomfort; freedom from pain, injury and disease; freedom to express normal behaviour; and freedom from pain and distress.

114 Food Ethics Council. After FMD: *Aiming for a Values Driven Agriculture*, 2001; and *Farming Animals for Food: Towards a Moral Menu*, 2001.

115 Animal Procedures Committee. *Report on Biotechnology*, June 2001.

116 FAWC. *Farm Animal Welfare and the Future of Farming and Food*. Submission to the Policy Commission on the Future of Farming and Food. 30 November, paragraph 10. Available at [www.fawc.org.uk](http://www.fawc.org.uk)

173 We believe that the new strategic body could be asked to advise on this area. It would be able to compare and contrast how this was being done across the different areas of society's relationships with animals. And we would expect that the issue of adequate enforcement of farm animal welfare regulations will be looked at by Government in the context of the recommendations of the Policy Commission on the Future of Farming and Food about farm quality assurance schemes and recommendations of the inquiries into the 2001 outbreak of foot and mouth disease.

## **PART 2.5**

### **RESPONSIBILITIES WITHIN GOVERNMENT**

- 174 Responsibility for the welfare of farm animals and, since June 2001, for pet and other animals, rests in the UK Government with DEFRA. Research animals continue to be the responsibility of the Home Office throughout Great Britain. In Northern Ireland the Animals (Scientific Procedures) Act 1986 is administered by the Department of Health, Social Services and Public Safety for Northern Ireland, under the Minister who is accountable to the Northern Ireland Assembly.<sup>117</sup> Responsibilities for other animals and activities involving animals are devolved.
- 175 The division of responsibilities in Government for animal welfare is not central to our examination of animals and genetic biotechnology. We nonetheless make the observation that in principle it would be better for the government department with responsibility for the welfare of a particular type of animal to be different from the department which sponsors the industry making use of that group of animals, to avoid a potential conflict of interest. We have noted, however, in relation to farm animals, that DEFRA includes in its main objectives one relating in part to maintaining high standards of animal health and welfare. We also note that the DEFRA Management Board has the Director General of Animal Health and Welfare, who is also the Chief Veterinary Officer, as a Management Board member. We further recognise that it is too early to judge the effect on departmental culture and ways of working of bringing together elements of the former DETR and Home Office with MAFF.
- 176 We do not believe in any case that a further organisational disruption relatively soon after the last machinery of government change is likely to serve farm animal welfare or the legislative review of animal welfare legislation well in the short term. We have not recommended, therefore, at this time that responsibility for farm animal welfare should be split from agricultural industry sponsorship. We have however noted wider public distrust of government as a regulator of agriculture. One consequence of this was the creation of the Food Standards Agency, which operates independently of other government departments. But people will be looking for evidence that DEFRA is up to the challenge in this area and anticipate that the possibility of separating the responsibilities will be revisited by the new strategic body if this evidence is not forthcoming. The same principles apply to giving and being seen to give adequate consideration to animal welfare in the devolved administrations.

<sup>117</sup> In that respect day to day administration/implementation is devolved. There are some areas of joint responsibility, chiefly as regards appointment to and advice from the APC.



**ANNEXES**



## **ANNEX A**

### **DESCRIPTION OF THE PRESENT REGULATORY FRAMEWORK**

#### **LEGISLATION**

- 1 The regulation of activities involving GM and cloning and animals is designed to achieve at least three different objectives: to minimise the risk to human health; to minimise the risk of harm to the environment; and to ensure that animal welfare considerations are taken into account. This is achieved in part through a combination of legislation and regulations that are specific to biotechnological processes, and partly through laws, regulations and codes of practice which apply both to GM and cloned animals and to conventional animals.
- 2 At present, all animals used for experimental or other scientific purposes, including GM and cloned animals, are protected in the United Kingdom by the **Animals (Scientific Procedures) Act 1986 (A(SP)A)**.<sup>118</sup> This requires that any experimental or other scientific procedure which may cause pain, suffering, distress or lasting harm to a protected animal must be licensed by the Home Office or, in Northern Ireland, by the Department of Health, Social Services and Public Safety for Northern Ireland. The Act applies until the death of the animal unless the animal is specifically discharged. At present all activities involving the creation or subsequent breeding of GM animals, and all cloning and breeding of animals for xenotransplantation, are governed by the provisions of the Act, because they are being undertaken for scientific or other experimental purposes. GM and cloned animals covered by A(SP)A are also in some circumstances covered by the Protection of Animals Act 1911 (see below), as are conventional animals.<sup>119</sup>
- 3 Offspring from GM animals are treated as genetically modified (even if one parent is unmodified and even if they are subsequently bred by conventional means) and come under the control of A(SP)A unless or until they are discharged. Before considering discharge, the Home Office will require, as a minimum, welfare records for two generations of animals living a full lifespan. No GM animal has been discharged to date.<sup>120</sup>
- 4 Establishments where genetic modification is undertaken, or where GM animals are kept or reared, are also regulated by the **Genetically Modified Organisms (Contained Use) Regulations 2000**, which implement EU Directive 98/81/EC. The Contained Use Regulations apply to all GM organisms. These regulations are concerned with protection of **human health and safety** from all GMOs (including GM animals); and protection of the **environment** from the contained use of GM micro-organisms only (not GM animals). The degree of containment of the GM animal is determined by the assessment of the risk to human health. The regulations are enforced by the Health and Safety Executive
- 5 These regulations cover the original creation of a GM animal and any breeding from it which is carried out in containment including all GM animals supplied by others except animals that have a marketing (Part C) consent granted under the EU Deliberate Release Directive (there are none at present).

<sup>118</sup> The use of animals for experimental or other scientific purposes as regulated by A(SP)A is not a devolved matter.

<sup>119</sup> Section 22(5) of A(SP)A makes provision for offences under the 1911 Act in respect of an animal at a designated research establishment. This is as one would expect: the 1911 Act applies to most farm and companion animals, even if some of those animals are also subject to agricultural or other regulations which are designed to protect the animals' welfare.

<sup>120</sup> If GM animals were discharged from A(SP)A, they would still be subject to the Contained Use Regulations (see paragraphs 4-5 below) if they are held in contained premises, or a consent would have to be obtained under the Deliberate Release Regulations (paragraph 7 below) before they were released into the environment.

- 6 **Part VI of the Environmental Protection Act (EPA) 1990 and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996** require an assessment of risk to the environment for each activity involving GM animals (although there is no requirement to notify anyone of that risk). This is then used in part to determine what type and level of containment is most appropriate.<sup>121</sup> The focus of these regulations and the risk assessments is on plants rather than animals.

### Deliberate Release into the Environment

- 7 It is an offence under Part VI of the EPA to release a GMO into the environment without the prior consent of the Secretary of State or the National Assembly for Wales or the Scottish Executive in Wales and Scotland respectively. Such releases are regulated by the **GMO (Deliberate Release) Regulations 1992** (as amended in 1995 and 1997). New regulations will be brought into force in 2002 to implement the revised EU Directive EC/2001/18 on deliberate release. Deliberate Release regulations are concerned with protection of the environment and human health and safety in relation to GM organisms. The revised European Directive EC/2001/18 includes, among other changes, a new requirement for a risk assessment of long-term and indirect environmental effects prior to release and mandatory post-commercialisation monitoring of environmental impacts.

### International trade in GM animals

- 8 If a GM animal received Part C consent in any EU Member State, it could be imported for marketing or release into the UK. (GM animals imported only into contained use - see paragraph 4 - facilities do not require Part C consent.)
- 9 Under the **Biosafety Protocol 2000**,<sup>122</sup> any country exporting a GM animal for release into the environment will be required to give advance notice to the importing country. Although it has yet to be ratified, existing EU legislation already requires this in respect of imports into the EU. Proposals from the European Commission for applying the protocol to exports from the EU were published in February 2002. There are funds under the protocol to assist with capacity building in developing countries. The clearing house for information provides information about which GMOs have approval for release in other countries (at present, only plants). The Protocol and in consequence the proposal on Regulation to implement those parts of it not yet covered by existing European Community law<sup>123</sup> are considered to encompass GM semen, ova or embryos.<sup>124</sup> Cloning does not fall within the scope of the Protocol.

<sup>121</sup> There are also regulations about the question of the use of GM animals for food or animal feed. Any food derived from a GM or cloned animal (including a fish) would be covered within the definition of a novel food. Approval would be needed at European Community level before such foods could enter the food chain. The Advisory Committee on Novel Foods and Processes (ACNFP) advises the central authorities in England, Scotland, Wales and Northern Ireland on UK applications. Any food derived from a GM (but not a cloned) animal would also need to be labelled under the present arrangements and proposals on labelling (these do not include products from animals fed on GM feed but not themselves GM). To date, there has been no application made in the UK to have GM animals enter the human food chain, although the general question was first examined in the early 1990s under the auspices of the ACNFP. In any case, all mammals, whether GM or not, are prohibited from being used as food for agricultural livestock as part of the controls following the BSE epidemic. So there is no question of GM mammals being used as feed for agricultural animals at present. The Advisory Committee on Animal Feeding-stuffs (ACAF) advises DEFRA and the Food Standards Agency on safety aspects of all novel animal feeding stuffs, which would include materials derived from GM animals.

<sup>122</sup> [www.biodiv.org/biosafety/protocol.asp](http://www.biodiv.org/biosafety/protocol.asp)

<sup>123</sup> DEFRA launched a consultation on the implementation proposal in July 2002.

<sup>124</sup> Sperm, ova and embryos are not explicitly mentioned in the definitions (Article 3, Use of Terms) in the Protocol but would seem to be covered by the term 'Living Organism' in the Protocol, which is defined as 'any biological entity capable of transferring or replicating genetic material'. 'Living Modified Organisms', the subject of the Protocol's provisions for international monitoring, would therefore cover GM sperm, ova and embryos.

- 10 The Home Office authorises the acquisition and use of a GM or cloned animal imported into the UK for experimental or scientific purposes (but not the importation itself). Similarly, GM and cloned animals can be exported to an overseas laboratory, with Home Office approval, at which point A(SP)A ceases to apply to those animals.

### **Xenotransplantation**

- 11 The **UK Xenotransplantation Interim Regulatory Authority** (UKXIRA) is responsible for advising Ministers on the action necessary to regulate xenotransplantation; and any specific applications to carry out a xenotransplantation procedure on humans (unless it was gene therapy) would be made to UKXIRA. Any GM animals created for the purposes of xenotransplantation research are covered by A(SP)A and would also be covered by the Contained Use Regulations unless they received Part C consent for release under the Deliberate Release Regulations.<sup>125</sup> There is no commercial work or research using pigs going on at present in the UK as was the case formerly, although related research with mice continues here.

### **General animal welfare legislation**

- 12 All farm, pet, zoo and sporting animals are protected in England and Wales by the provisions of the **Protection of Animals Act 1911**. In Scotland the Protection of Animals Act (Scotland) 1912 gives effect to the same provisions and hereafter 'the 1911 Act' should be understood as including both Acts. The 1911 Act makes it an offence to cause unnecessary suffering to any animal. Northern Ireland has similar (but expanded) provisions in the Welfare of Animals Act (Northern Ireland) 1972, which replaced the majority of the 1911 Act in Northern Ireland. The 1911 Act is used in England, Scotland and Wales by, among others, the State Veterinary Service (SVS), the Royal and the Scottish Societies for the Prevention of Cruelty to Animals (RSPCA and SSPCA), the police and local authorities, when bringing prosecutions for cruelty to animals.
- 13 As noted earlier, GM and cloned animals are protected by general animal welfare legislation as well as coming under the provisions of A(SP)A. If a GM or cloned animal were to be discharged from A(SP)A and released into the environment (with an appropriate consent), or if genetic modification ceased to come within the remit of A(SP)A, the GM or cloned animal would continue to be governed by the general animal welfare legislation.

### **Farm animal legislation**

- 14 GM animals which fall within the definition of 'livestock'<sup>126</sup> are covered by the **Agriculture (Miscellaneous Provisions) Act 1968**, under which it is an offence to cause unnecessary pain or distress to any livestock kept on agricultural land. The **Welfare of Farmed Animals (England) Regulations 2000** enacts various EU directives about farm animal welfare, including EU Directive 98/58/EC, which sets out general rules for the protection of animals (including fish) kept for farming purposes with separate directives governing laying hens, calves and pigs. Similar legislation has been enacted in Scotland, Wales and Northern Ireland.

<sup>125</sup> Conventional animals bred and reared by conventional breeding methods for medical purposes (e.g. heart valves) are outside the scope of A(SP)A and are governed by general animal welfare legislation.

<sup>126</sup> 'Livestock' are defined as animals 'kept for the production of food, wool, skin or fur or for use in the farming of land'.

This legislation would not apply to GM animals in pharming if and when they were discharged from A(SP)A because the animals would not be classed as livestock kept for an agricultural purpose. But it would apply to other GM or cloned farm animals.

- 15 Law relating to animals is most commonly made at EU level. Member States are obliged to transpose EC directives into national law. In addition, the Council of Europe has five Conventions covering animal welfare, including one on the **Protection of Animals kept for Farming Purposes** and also one on the **Protection of Pet Animals**. The EU (and individual Member States) is obliged to abide by World Trade Organisation rules in drawing up legislation.

## ADVISORY BODIES

### Farm animals

- 16 The Farm Animal Welfare Council (FAWC) was set up in 1979. It is a non-statutory advisory body whose operation is funded by DEFRA. Its terms of reference are ‘to keep under review the welfare of farm animals on agricultural land, at market, in transit and at the place of slaughter, and to advise the Government of any legislative or other changes that may be necessary’. The Council can investigate any topic falling within its remit, communicate freely with outside bodies, the European Commission and the public and publish its advice independently.
- 17 FAWC operates by making reports, which can form the basis for Codes of Practice for England which are prepared by DEFRA and laid before both Houses of Parliament for affirmative resolution. A similar mechanism is employed in the Scottish Parliament and the National Assembly for Wales. Like the Highway Code, these Codes can be taken into account in Court although failure to comply with them is not an offence in itself.

### Pets

- 18 The Companion Animals Welfare Council (CAWC) is a voluntary body set up in 1999 and neither it nor its reports have any formal status. Its members were chosen by a panel set up, though not by Government, for the purpose. CAWC receives no Government funding. It hoped when it was set up to receive Government funding in the same way as FAWC but when this was not forthcoming its founders launched it anyway, in the hope that if it proved its worth by the reports it produced, then it might attract Government sponsorship similar to FAWC.

### Research animals

- 19 The Animal Procedures Committee (APC) advises the Home Secretary and the Department of Health, Social Services and Public Safety for Northern Ireland on matters concerned with A(SP)A and Ministerial functions under it. The APC has an obligation to have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

### **Containment/deliberate release of GM animals**

- 20 In respect of the contained use of GM animals, the Health and Safety Commission is advised by the Advisory Committee on Genetic Modification (ACGM).
- 21 The Advisory Committee on Releases into the Environment (ACRE) advises Government on applications for the deliberate release of GMOs into the environment. To date no application to release a GM animal has been made.

### **Enforcement**

- 22 There are different enforcement bodies whose work is relevant to animals and biotechnology. Home Office officials are responsible for enforcing regulation on research animals. Specialist inspectors from the Health and Safety Executive enforce both the Contained Use Regulations and Part VI of the EPA 1990 on behalf of the Department for the Environment, Food and Rural Affairs (DEFRA). Outside the field of research, for farm, pet and zoo animals, enforcement of legislation falls variously to local authorities, the police and the State Veterinary Service, with animal welfare societies, principally the Royal, Scottish and Ulster Societies for the Prevention of Cruelty to Animals (RSPCA, SSPCA and USPCA respectively) also playing an independent role.
- 23 The veterinary profession also has a role in aspects of applying GM and cloning. The Veterinary Surgeons Act 1966 requires that invasive surgical procedures are carried out only by qualified veterinary surgeons. Where procedures such as embryo transfer, as part of GM or cloning, fall into this category, then a qualified veterinary surgeon would be required to perform the procedure.

## ANNEX B

Literature review by Professor Breakwell for the Agriculture and Environment and Biotechnology Commission sub-group on animals and biotechnology.

### RESEARCH IN THE UK ON PUBLIC ATTITUDES TO BIOTECHNOLOGY WITH ANIMALS

The following strategies have been pursued to identify the research that has been done in the UK concerning public attitudes to biotechnology with animals since 1990. Clearly there can be no guarantee that it has all been successfully identified. However the following strategies were adopted to maximise the likelihood of this.

- 1 Contacting relevant organisations: e.g. EC, ESRC, BBSRC, MRC, MORI, MAFF, International Research Group on Biotechnology and the Public; the Animal Procedures Committee; the National Centre for Social Research; the Human Genetics Commission; the Office of Science and Technology; RSPCA; Compassion in World Farming; the Institute for Environment, Philosophy and Public Policy; the Farm Animal Welfare Council.
- 2 Contacting individuals who have done work in this or related areas: e.g. John Durant, Lynn Frewer, Dick Shepherd, Joyce Tait, George Gaskell, Nick Allum, Donald Bruce, David Heaf, Michael Appleby.
- 3 Doing web and literature searches using key words in Psychlit and the Web of Science, checking the contents pages of relevant journals.
- 4 Checking studies identified in Public Opinion about Biotechnology: a Survey of Surveys (1998), The Hague: European Federation of Biotechnology, Task Group on Public Perceptions of Biotechnology.

The terms of reference for this review did not include an evaluation of the methods or the interpretative frameworks adopted by the studies. It would be useful for such an evaluation to be seen as an adjunct piece of work.

Having conducted this review, the authors of this report are now in a position to make recommendations concerning the appropriate methods and focus for future work in this area.

#### Introduction

It is increasingly considered to be crucial to understand public attitudes to biotechnology with animals in order that policy making bodies can be proactive, anticipating rather than simply reacting to public debate (Freeman, 2000). It has been suggested that it is important to heed the warnings signalled by public opinion. The 1996 Eurobarometer flagged up the public opposition to the use of transgenic animals in medical research and the concern about agricultural and food biotechnologies. The latter two applications have subsequently been beset by controversy. With the impending commercialisation of the genetic modification of animals (Freeman, 2000), both industry and regulators need to be aware of the nature and strength of public attitudes in this area: the 'second hurdle' (Gaskell, Allum, Bauer, & Durant, 2000).

Groups in this area have recognised the pivotal role of public attitudes and stressed the need for the provision of appropriate and understandable information about the role of genetic modification of animals and their products (Group of Advisors on the Ethical Implications of Biotechnology, 1998). Views of the public and various interest groups have been elicited by the Animal Procedures Committee and this report should be in the public domain within the next month. Pressure groups such as the British Union for the Abolition of Vivisection and Compassion in World Farming believe “ an extensive public information and consultation programme is urgently needed in this area”<sup>127</sup>

Overall, there would seem to be little research in this area in the UK - indeed it appears that the issue of animals and biotechnology has not formed the sole focus of any research. Rather the issue has been addressed within research that has a different, or broader, focus such as biotechnology in general or animal welfare. There are a variety of animal applications of biotechnology (Freeman, 2000; Mepham, 2000a; The Boyd Group, 1999). There has been no systematic research that looks at public attitudes to each of these. There has been some research in these areas in the US (Singer, Corning, & Lamias, 1998; Hagedorn & AllenderHagedorn, 1997)

Ethical concerns are clearly dominant in any consideration of public attitudes to animals and biotechnology. When considering ethical concerns about the genetic modification of animals it is important to distinguish between (a) fundamental moral objections to the human use of animals generally, or (b) specifically to their genetic modification and (c) concerns about the consequences of genetic modification (The Boyd Group, 1999). It does not appear that there has been any research done that allows for exploration of public attitudes in all of these areas simultaneously or indeed that considers ethical concerns in a systematic manner (Mepham, 2000b; Mepham, Moore, & Crilly, 1996).

Two recent research projects on public attitudes to research with animals (not specifically involving biotechnology) have also been included in this review. The factors they examine and their conclusions would seem to be of some value in considering the more specific domain of biotechnology with animals.

A number of conclusions can be drawn from this review of the literature on animals:

- There is a particular negativity to animal biotechnology applications in the UK.
- Overall the UK public are more polarised in their attitudes than the average European.
- In determining the extent of public support, safety is seen as vital, but not sufficient.
- The main bases of judgement are whether the technology is useful and ethical.
- Perceptions of moral unacceptability ‘act as a veto’, even if the perceived risk to human health and the environment is low.
- When considering whether a biological development is right or wrong the possibility of animal harm is an important consideration.
- The public perceive a lack of information about animal biotechnologies.
- There are often gender differences with women viewing animal applications more unfavourably and being more concerned about animal welfare.

127 [http://www.ciwf.co.uk/Pubs/Reports/Animal\\_organ\\_in\\_humans.pdf](http://www.ciwf.co.uk/Pubs/Reports/Animal_organ_in_humans.pdf)

- The specificity of questions and the context in which they are placed affect expressed attitudes.
- Monitoring the acceptability of both products and processes is important.
- People evidence a complex pattern of reasoning knowledge and values; they are aware of inconsistencies and ambivalence and want to form opinions based on facts.
- Credible evidence of serious social justification of particular technologies is taken into account when people are forming judgements.
- It is important to systematically track changes in attitudes over time.

For each study used a number of parameters have been identified

- Researcher/Title
- Aim/purpose of research
- Area (of biotechnology)
- Type of research
- Sample scope: population group/sub groups
- Where research is reported
- Views of participants and factors influencing their views

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## ANNEX C

### DIGEST OF MACNAGHTEN REPORT ON CONTEMPORARY UK PUBLIC ATTITUDES AND SENSIBILITIES TOWARDS ANIMALS

Phil Macnaghten

## DIGEST

### Background

- This research report examines contemporary UK public attitudes towards animals, and in particular towards the prospective uses of animals as a result of continuing advances in biotechnology. It was undertaken by social scientists<sup>128</sup> at the Institute for Environment, Philosophy and Public Policy, at Lancaster University in July-October 2001.
- The study employed qualitative discussion group methods, interpreted sociologically, for a spread of social groups in the north and south of England. It builds on previous work by the researchers in other, parallel spheres of contemporary public sensibility.
- Each discussion group was set up to reflect a different balance of elements, involving both a variety of specialist relationships with animals, and broader connections with animals as pets. Methodologically, situations were set up in which people could talk about animals in different spheres of daily life, in their own terms, and subsequently to explore how people responded to potential human uses of animals arising from biotechnological applications, and the factors shaping such responses.
- The concern of the study was to throw light on how people feel about:
  - (a) their everyday experience of and relationships with animals - as pets, as wildlife, and in work and sporting contexts; and
  - (b) prospective increases in the use of animals to take advantage of recent and continuing advances in biotechnology, and in particular genetic modifications.
- The study, based on a necessarily limited sample of population groups, is seen as providing an initial snapshot rather than a definitive analysis.

### Findings

- Many people have close, affective relationships with animals in domestic and other contexts.
- People recognise frequent personal contradictions in their behaviours towards animals, moving between close, even intimate and inter-dependent family connections, and exploitation for food, for clothing and as 'surrogate' humans in scientific testing. A degree of 'denial', and even hypocrisy, in this regard is frequently acknowledged. Such reactions appear to signal shifting social awareness of the tensions between 'moral' and 'instrumental' approaches to animals in modern society.

<sup>128</sup> In addition to Phil Macnaghten, Majid Yar participated in the research process.

- The discussions suggest there is only limited appreciation in the UK of the extent and character of persistent patterns of animal use for experimental and testing purposes. In general, people's attitude towards animal testing depends critically on the use to which the research is oriented. In this regard, people feel less uncomfortable about animal testing for medical purposes than for *cosmetic* purposes. However, there appears to be an emerging acknowledgement of the difficulty of maintaining such clear-cut distinctions.
- The prospective use of animals to take advantage of contemporary developments in biotechnology tends to be interpreted by people in the light of their attitudes to *existing* practices and relationships. Some discomfort is evident when people come to think about such matters, but with this comes recognition that open and considered public debate about the issues is now appropriate.
- People's attitudes towards such matters are influenced by their perceptions of the *purposes* of the research or exploitation processes involved. This issue of 'justification' seems likely to pose challenges for present apparently clear-cut distinctions between the medical and other (e.g. cosmetic) benefits.
- Animal testing arising from advances in the new genetics for 'medical' purposes arouses ambivalence. A minority appear to be opposed in principle; but a need for greater official openness about 'what is actually going on', including a clear justification of the 'usefulness' of such research, and for regulation grounded more firmly in human/moral criteria rather than scientific/commercial necessities, is felt by many to be appropriate.
- Most people regard the direct genetic modification (GM) of animals as both 'new' and 'unnatural'. Although few people rejected the use of this technology *tout court*, there is considerable concern about the speed and pace of such developments, the degree of intervention and precision involved, and the anticipated likelihood of unanticipated mistakes. Key conditions for acceptable use of GM animal technology include the requirement to demonstrate a *genuine and authentic* need for undertaking such procedures, commensurate with such concerns.
- Public concerns to GM animal technologies can be seen to encompass a number of distinct elements. Firstly, they include concerns about the intrinsic character of animals, including the need for animals to retain their integrity. Secondly, they encompass concerns about animal welfare, about the maintenance of standards of care in the treatment and use of animals. And thirdly, they embrace a range of additional issues pertaining to the surrounding conditions of regulation and institutional oversight.
- The misgivings people express towards the applications of GM animals appear to be reflections of broader syndromes of mistrust towards those institutions seen as responsible for such applications. Repeatedly, the crises over BSE and GM foods were invoked in support of suggestions that key institutions responsible for overseeing such innovations are not to be trusted. Perceiving such institutions as being 'in denial' of what was at stake in such technological advances - both morally and consequentially - exacerbated people's sense of the likelihood of subsequent unanticipated mishaps.

- However some differences of attitude prevail, largely dependent on the work practices of the individuals involved. Farmers are more likely to see GM animals as further stages in selective breeding - though this in turn is seen as unlikely to bring benefits for most *existing* farmers in their real-world circumstances.

### Potential Implications

- There thus appears to be potential scope for controversies to arise in the GM animals and the genetic testing domains. Whilst there appears from the groups to be little outright rejection of such practices, people's personal unease at their own contradictory behaviours towards animals appears to be combining with pressure for greater public disclosure of the levels and patterns of experiments to create potential tensions.
- Moreover, if the overall advantages to society of 'the new genetics' becomes itself a focus of public questioning - as some of the discussions appear to imply is now possible - then vulnerabilities for public controversy will tend also to increase, even in the medical domain.
- There is an evident need for openness and informed public discussions of these matters if socially resilient ground-rules for future use of animals in biotechnology are to be developed. At present, most people feel 'in the dark', and hence suspicious, despite an evident willingness to strike 'reasonable' balances between animal welfare and technical advances.
- This offers a timely reminder of the case for implementing new ways of engaging public opinion, prior to any publicly damaging controversy. Furthermore, regulatory systems need to get to grips with the key *conditions* underpinning the public acceptability (and unacceptability) of GM animal technologies. There is an urgent requirement both to identify what these conditions are, and to support and cultivate government action to ensure such conditions prevail.

## **ANNEX D**

### **EXECUTIVE SUMMARY OF THE FINAL MORI REPORT ON THE AEBC REFERENCE GROUP ON ANIMALS AND BIOTECHNOLOGY**

**Michele Corrado, Sarah Hackworth, Louise Vinter**

**This is the executive summary of the third workshop, held in February 2002, in a series of three, conducted by MORI among a Reference Group convened on behalf of the AEBC**

Participants were, as on the previous two occasions, split into 3 mini-groups for much of the discussion. The three groups were each given different topics for discussion.

- How well do you think the concerns expressed by you and the Reference Group as a whole fit into the AEBC's thinking as outlined by you?
- How well are the concerns expressed by the Reference Group answered by the AEBC's proposals for the regulatory structure?
- Forms of public involvement.

The overlap between the first and second topics, however, was great and therefore these findings have been reported on together in this summary. In addition, since the afternoon was spent discussing each of the three topics in a plenary session, every member of the Reference Group was given the chance to give opinions on each of the points of discussion. The following summary is therefore arranged thematically, rather than taking the three groups separately by topic.

#### **THE CURRENT SYSTEM**

The current regulatory system was not discussed at length as this had been done at the first workshop in October 2001. The main concerns voiced in October had been that the present regulation of biotechnology in application to animals is excessively bureaucratic, confusing and difficult to comprehend in practice, based on out-dated laws (notably on the 1911 Animals Act), and stereotypes of ineffectual public committees were quickly attached to it. The over-riding conclusion was that the public do not have enough information about the actual uses of animals, or about those responsible for monitoring and protecting them.

In the third workshop, participants were given diagrams of the current system and the existing regulation of GM and cloned animals (group participants found this particularly difficult to understand).

Participants were equally negative towards the current system in February 2002 as they had been in October 2001. The concerns they had expressed in October (which had at the time been mainly based on relatively scant knowledge and assumptions) were, if anything, borne out by the details displayed on the diagrams.

These concerns were:

- There were felt to be too many advisory bodies. Participants were concerned that there are not enough bodies with powers of enforcement or decision-making (a priority identified in October). Participants felt that the current set-up involving the APC, ACGM, ACRE and UKXIRA cannot carry sufficient power, particularly in relation to research - UKXIRA being the only body with regulatory powers. As a result the system was perceived to be ineffectual.
- Participants found the system confusing (despite the diagrams) - commenting that there were too many separate bodies and not enough co-ordination between them. Some confusion may have been a response to the concept of having a single over-arching body (presented at the earlier workshop).
- The Government was seen to play too great a role, being seen as the centre of the process, to which all bodies report to directly. Independence from government is a key priority for members of the public when making a judgement about a regulatory or advisory body; this criterion had been identified in October and was quickly applied to the diagram shown in February.
- Many questions remained about the ability of the system to provide adequate evaluation of the issues, to set appropriate rules and standards, and enforce them thereafter. Despite AEBC assurances that enforcement agencies such as the Home Office Inspectorate and local authorities are very effective, participants' distrust remained, due to an ingrained scepticism about the effectiveness of the current system.

## THE NEW STRATEGIC BODY

In October, many participants had been spontaneously enthusiastic about the idea, albeit a vague idea, of an 'over-arching body' to cover all aspects of animals, including biotechnology. The new, embellished proposals were put to the Reference Group in February, and expressed visually in a diagram. The purpose of the new strategic body was summarised as being to bring all existing regulatory and advisory organisations under one umbrella, to define the ethical and practical 'rules' to which all organisations should work - in other words, to create a unified regulatory structure working to one set of standards. Under this umbrella body, the existing regulatory and advisory bodies would remain. The new body would look at the 'big picture', taking a strategic view of animals and biotechnology now and in the future. It would provide independent advice to the government.

Participants' reactions on hearing more detail about the 'new strategic body' were initially cautious, ranging from disappointment at certain details, to high (but not unreserved) approval. Over half were on balance positive, but retained some concerns, and most others were more forthright in expressing reservations. Nobody gave their unqualified approval. Reservations did not arise from a waning in enthusiasm for the principle of an over-arching body, but rather because some aspects of the strategic body were not as participants had hoped or anticipated based on the ideas they had discussed in October 2001.

One participant summed up the feelings of the whole Reference Group fairly well when she said *'it seems like a good idea, but watch this space...'*

## CONCERNS

- The most common, and most vehemently expressed concern was that the strategic body as proposed by the AEBC would not have regulatory powers, but would be ‘yet another’ advisory body. One of the most important characteristics of the ‘ideal’ body in participants’ minds in October 2001 had been that it would have an impact. The terminology - ‘advisory’ immediately gave rise to doubt that this could be the case. For three or four participants this was a nail in the coffin, as they saw ‘actual’ power as a prerequisite to making a difference. A purely advisory body, as they saw it, would have a *‘lack of teeth’*. This perception seems to come from an ingrained assumption that advisory public bodies are simply layers of bureaucracy and government pawns, rather than independent organisations having important effects. Power is equated, in this assumption, with ‘teeth’. Participants wanted to know the exact status of existing bodies, and some idea of how much they are actually listened to. Some participants in one group compared the strategic body to OFSTED. Their ideal body would be feared, as OFSTED is, by those who came under its umbrella.
- In the February workshop, participants engaged in extensive discussion with the AEBC representatives about the pros and cons of advisory or regulatory bodies. Participants put forward their concern that an advisory body would not be capable of having any real effect on the course of events. The counter arguments put to them by the AEBC included the point that advisory bodies can have ‘teeth’. It was also mentioned that since the BSE crisis the government has changed the way it handles scientific advice, giving greater scope for conflicting views to be taken into account, advisory bodies playing a role here. The AEBC representatives drew attention to the fact that the labels ‘regulatory’ and ‘advisory’ might have overshadowed the discussion. In fact the key issue was whether or not the new strategic body is fit to decide what happens to animals. Enforcement of existing regulations would be an important facet of this, and an advisory body would be in a tactical position to put pressure on those agencies responsible for enforcement. In addition other stakeholders, farmers and industry in particular, would be averse to yet another layer of regulation.
- These arguments were encouraging for many participants, and caused their scepticism about creating an advisory body to subside. The AEBC also indicated that being listened to and having the resources to fulfil recommendations are pivotal to the success of the body, rather than the label it is given. This was felt to be an acceptable compromise by some participants.
- The role of government was the second most common cause for questioning and concern. Groups one and two (discussing the extent to which the AEBC’s proposals had addressed their concerns about the regulatory structure) immediately asked why in the diagram shown, the strategic body did not sit between the specialist bodies and the government. The proposed structure, in which communication happens directly between each of three parties (strategic body, government and individual bodies) with no channels of communication being shut off, did not appear to fit with the participants’ preconceptions that government should be kept out of the loop. In particular, this focussed on a belief that governments keep information behind closed doors or disclose snippets (but only snippets) selectively as and when it suits their purposes. In addition, participants feared the body would become a government mouth-piece. Their approach to this was a *‘we’ll believe it when we see it’* approach. Around half took on board the argument that placing the new body between existing bodies and the government would simply add another new layer of bureaucracy, and acknowledged that specialist bodies must be able to communicate directly with government. However, the distrust in governments’ reliability to be free and open, that was expressed so vociferously in both July and October, was clearly borne out

here in participants' quick condemnation of the prominence of governments in the proposed picture. The AEBC pointed out that the Government was a necessary part of the loop, and that any new body would have to liaise closely with governments. Participants reluctantly accepted this point, recognising that ultimately the public has to put its trust in the Government as the final source of power.

- A question was raised by the AEBC to participants about whether the public lacks faith in governments on anything (not just science). Participants conceded that the public generally lacks faith in governments on anything. The AEBC asked if this distrust was a reason behind enthusiasm for a regulatory body, and most participants agreed that it is.

## MERITS

- While the negative reactions were strong and almost overwhelming, they were confined to the points above. Overall, more positive points were made than negative.
- There was a fair amount of concurrence in the view of the proposed strategic body that *'it's good that it exists'*. While only a couple of participants voiced this view spontaneously, it met with approval from other participants, and none said they would wish to keep with the existing structure. All discussion seemed to be conducted over the base assumption that an umbrella organisation would be a positive addition. This matched with views expressed in October, and as before, caveats were placed on the details of the new body, rather than doubt expressed about its existence.
- The combining of biotechnology and non-biotechnology issues relating to animals was not questioned by any participant and might therefore be seen to have been implicitly endorsed. While this sits well with participants' views that animal welfare should be taken care of (whether the animals have been genetically modified or not), their views have also been arrived at through their having little knowledge about biotechnology. That is, they may not have questioned the idea because they were not in a position to do so.
- The 'umbrella' nature of the body was unanimously popular, and seen as matching well with participants' own preconceptions of how it should be formed, as expressed in October. One reason for the positive reaction to this feature was that consistency of policy and information are considered key priorities by members of the Reference Group. Enhanced communications were envisaged as a primary function of the body by participants. This was a view that had not emerged explicitly in October, and it seemed to be prompted by the diagrams of the current system introduced in February.
- The strategic responsibility for ethical considerations received approval for the same reasons, particularly because group members commented that there is no-one to do that at present.
- The flip side of the coin is that specialist influence over specialist issues would be maintained by preserving the existing bodies, and this was viewed positively by participants.
- The mechanism for increased public consultation was perceived to be a strength of the strategic body, both from the point of view of improving public understanding, and from that of facilitating a two-way communication process between the public and those in influential positions. Otherwise the body will *'disappear into a big nothingness'*.
- Participants were very keen that the body should perform a validation role over the enforcement agencies, again revealing the common disbelief that sufficient checks are made at present.

- Participants asked what the composition of the body would be, as the AEBC had not covered this in their presentation, and it had been the focus of some heated discussion between participants in October. On hearing from the AEBC that many different groups would be represented, participants were happy that the body would represent each of the groups they had identified in October, and the discussion moved on.
- One group stressed that the new body must *'lead not follow'*. It must be a forum for generating new ideas.

## OTHER ISSUES

- International co-operation was considered a crucial component of a successful regulatory system by all participants. There was quick approval for the idea of a 'gold standard', or code, to which all countries should adhere. Participants based this on the understanding that so long as scientific knowledge advances, there will be ethical and economic considerations. However some felt that the differential standards in other countries would override everything the AEBC was proposing, enabling overseas companies to undercut UK ones. For example, they debated the dilemma posed by a potential UK ban on imports from a particular developing country due to that country's treatment of animals, and acknowledged the difficulty in striking a balance between taking a responsible attitude towards developing countries, i.e. helping their economies and taking a stance on animal issues. This was not a point that was laboured and most participants were not able to form strong views either way on the topic, but it was a significant concern and thus important to flag.
- Actual impact and real results are concepts participants repeatedly raised. The AEBC put forward several arguments to the Reference Group on this point. For example, in the face of opposition from other stakeholders to a regulatory body, the government needs to be pragmatic about the body that it creates. In addition, the role and remit of any body that is created can be reviewed after a period of time to check that it is doing the job it was set up to do. The general view amongst participants was that the proof will be in the pudding, and nothing will convince them to give whole-hearted approval until then.

## QUESTIONS

Participants raised some points that they did not feel able to debate, but would have liked to had they had more information, or had the AEBC's proposals been at a more advanced stage. These were as follows:

- How will the body be resourced? Will there be sufficient resources to implement recommendations?
- Who will sit on the body?
- What impact would recommendations made by the body have on actual policy? (Participants repeatedly expressed scepticism on the advisory nature of the proposed body).
- Could other bodies by-pass the strategic umbrella organisation if they so wished?
- Where will the EU come into the equation? (There were worries that the EU may override the body's recommendations).
- What provisions are there for future public involvement?

The AEBC's response to these questions was that they are details yet to be finalised, and that the views of the Reference Group would be taken into consideration, along with other factors, when the decisions were made.

## FORMS OF FUTURE PUBLIC INVOLVEMENT

- Since members of this Reference Group have become 'semi-experts' in public consultation, having been part of the group for eight months, their perceptions of 'the public interest' are likely to have been affected quite markedly. However, the following points were made about ways of consulting the public, and of encouraging public interest in the issues.
- The distinction was made between keeping the public informed, and getting them involved. Views varied on the extent to which the public needs to have actual involvement, but there was consensus that, most of the time, being kept informed is sufficient. Approximately one quarter wanted actual involvement, half wanted information only, but no involvement, and the final quarter preferred to '*leave it to the experts*', indicating that they might be happy without even any information.
- Participants also acknowledged that scientists can genuinely interpret scientific fact differently, and that there is not always a definitive understanding of a problem. As a result, informing the public is not straightforward.
- Provision of information is key, and can often pre-empt problems or criticisms.
- The use of television to convey messages was identified as the most effective method, due to its being direct, and minimal-effort for the public. In the second workshop in October, one participant suggested putting a story line in *Eastenders*, as the highest impact method of getting people interested. This time, *Question Time* was suggested as a good forum for announcing the establishment of a new strategic body.
- The view was expressed that the public should hear about positive developments in science rather than just '*when it goes wrong*' or '*scare stories*' like GM foods. However, it was acknowledged that newspapers are more inclined to report the latter.
- The body needs to be easily contactable by the public through a variety of media including the Internet and public libraries. It was argued, however, that these methods would only be effective if the public were engaged and interested in the first place.
- Leaflet and booklet drops are good ways of making direct contact, although participants feel that ideally this should be done after the initial television coverage of the issues; people would be more likely to read something if the issues were in the back of their minds to start with. Here the language issue was raised as a factor that needs to be taken into account, as ethnic minority communities are equally, if not more due to religious beliefs, likely to have an interest in the issues. MORI often finds that a leaflet drop through the door is the preferred method when people are asked how they would like to be kept informed.
- School science lessons are cited as the first point of contact with children. One comment was '*our future is in the hands of our children*'.
- With specific reference to the proposed strategic body, participants felt the public's goodwill depends to an extent on publicity in its early stages; a comment was made that if the public is made aware of its existence from the outset, it is more likely to trust it.

## CONCLUSIONS AND IMPLICATIONS

- Participants' views in the third workshop remained unchanged from the two previous occasions. Most importantly, central to their thinking was the need to ensure that scientists are properly monitored, and that medical research is deemed most important. The need for international co-ordination was also a key concern.
- Participants need assurance that the new body is going to have the authority not just to advise, but to intervene if they consider it appropriate and to liaise with all the other bodies that have a part to play with respect to animals. AEBC's response to these concerns had some positive effect on participants' views, but scepticism about how effectual the body will be will only be allayed by positive performance over time.
- The Reference Group would like both advice and regulations to relate to all kinds of animals, namely research farm, zoo, companion and wild animals, and marine life. Again, this remained unchanged throughout the course of all three discussion days.
- Another recurring theme, in relation to animal experiments specifically, was that participants tended to be more inclined to sanction experiments for medical purposes, and those which can enhance the quality of life. For this reason it is important for them to have information about the objectives behind experiments.
- The Reference Group had keenly hoped that any new body would have regulatory powers. Therefore the proposals for an advisory body did not sit with what the Reference Group had expected following their discussions in October 2001. As such, there was disappointment that the body would not have regulatory powers.
- Ideally, the Reference Group would like the body to be bold, as they understood this to be the only way that the body might actually make a difference. Discussion between participants and the AEBC highlighted that if this cannot be the case, there are a number of measures that can be taken to ensure that the body is seen by the public to be fit to address the issues that relate to animals. These are:
  - The body must be seen to be sufficiently independent from government to be able to make informed and objective recommendations. Crucially, it must be able to make them publicly, without any government input into its statements. The positive image of the body could be compromised if it was seen to be a cushion or mouthpiece for government.
  - The body must be seen to be in a position of strength. That is, it must be able to negotiate effectively on UK, EU and international platforms. This is crucial to the body being seen as effectual and worthy of creation in the first place.
- Another key conclusion must be that the AEBC's final report must ensure that it sends the public clear messages. It is critical that the public knows precisely what the new (advisory) body will do. Information need to be disseminated as fully and widely as possible, and go alongside interaction with the media. Many participants complained repeatedly that they only hear 'snippets' from the media, and usually the negative stories. Provision of information is key, and can often pre-empt problems or criticisms.

## **ANNEX E**

### **WHAT PEOPLE TOLD US**

#### **A WITNESSES WHO GAVE INFORMAL BRIEFINGS**

##### **Experts**

Professor Pat Bateson, Cambridge University and Chair of Royal Society working group on the use of genetically modified animals

Professor Donald Broom, Colleen McLeod Professor of Animal Health at Cambridge University and member of Animal Procedures Committee

Dr Donald Bruce, Director, Science, Religion and Technology Project, Church of Scotland

Professor Grahame Bulfield, Director, Roslin Institute and member of Animal Procedures Committee

Professor Stephen Clark, Liverpool University and member of Animal Procedures Committee

Dr Carey Cunningham, Fisheries Research Services, Scottish Executive

FAWC Research & Development Working Group

Professor Lance Lanyon, Dean and Principal, Royal College of Veterinary Surgeons

Dr Judy MacArthur Clark, Chairwoman, Farm Animal Welfare Council

Professor Ian McConnell, Cambridge University and member of Royal Society working group on the use of genetically modified animals

Dr Mike Radford, Aberdeen University

Lord Soulsby, Chairman, Companion Animal Welfare Council

Telephone conversations with relevant sporting industry bodies for equestrian sports, horse racing and greyhound racing

Telephone conversations with secretariat to Zoos Forum

##### **Industry**

Dr Gill Fleetwood, GlaxoSmithKline

Dr Ron James, PPL Therapeutics

Dr Margaret Landi, GlaxoSmithKline

Dr George Livi, GlaxoSmithKline

Dr Jim McKay, Vice President, Biotechnology, Aviagen Group

Graham Plastow, Director of Biotechnology Research, PIC Group

### **Trade Bodies**

Peter Bradnock, British Poultry Council

Ian Gardiner, National Farmers Union

Dr Jeff Kipling, Association of British Pharmaceutical Industries

### **Government**

Officials from the Department for International Development

Officials from DEFRA, including the State Veterinary Service

Officials from the Home Office

### **Interest groups**

Dr Martin Potter, Royal Society for the Prevention of Cruelty to Animals (RSPCA)

Joyce D'Silva, Compassion in World Farming

### **Others**

Colin Tudge, writer and freelance journalist

## **B PANEL MEMBERS AT AEBC PUBLIC MEETING IN EDINBURGH ON 23 APRIL 2001**

Professor Donald Broom, Colleen McLeod Professor of Animal Health, Cambridge University and member of Animal Procedures Committee

Professor Grahame Bulfield, Director Roslin Institute and member of Animal Procedures Committee

Joyce D'Silva, Director Compassion in World Farming

## **C ATTENDEES AT STAKEHOLDERS' SEMINAR, 9 NOVEMBER 2001**

### **Regulatory or advisory bodies or Government**

Dr Clair Baynton, Food Standards Agency

Professor Stephen Clark, Liverpool University and member of Animal Procedures Committee

Dr Judy MacArthur Clark, Chairwoman, Farm Animal Welfare Council

George Noble, DEFRA

Liz Sawyer, Advisory Committee on Genetic Modification, Health & Safety Executive

Glenda Townsend, DEFRA

Martin Walsh, Animal Procedures & Coroners Unit, Home Office

Laura Williamson, researcher to Professor Sheila Maclean, UK Xenotransplantation Interim Regulatory Authority

Dr Jon Tanner, Department for International Development

### **Scientists**

Professor Pat Bateson, Cambridge University and Chair of Royal Society working group on the use of genetically modified animals

### **Pharmaceuticals**

Barbara Holgate, Director, Biological Services, AstraZeneca

Jessica Hughes, GlaxoSmithKline

Dr Ron James, PPL Therapeutics

Brian Kirsop, Chair, Regulatory Affairs Committee, BioIndustry Association

Dr Timothy Morris, Head of Animal Ethics and Welfare, GlaxoSmithKline

### **Farmers, food industry & retailers**

Peter Bradnock, British Poultry Council

Alison Craig, representing Richard Young, farmer

Ian Gardiner, National Farmers Union

Dr Jim McKay, Aviagen Ltd

John Morris, Food and Drink Executive, British Retail Consortium

Chris Warkup, Meat & Livestock Commission

### **Interest Groups**

Joyce D'Silva, Compassion in World Farming

Patrick Holden, Soil Association

Dr Vicky Robinson, RSPCA

### **Others**

Dr Simon Festing, Association of Medical Research Charities

## **D FORMAL EVIDENCE OBTAINED AT AEBC MEETING IN BIRMINGHAM, 15/16 JULY 2001**

### **In private**

Dr Jon Richmond, Chief Inspector, Animals (Scientific Procedures) Inspectorate

### **In public**

Dr Paul Logan, HM Principal Specialist Inspector, Biotechnology Section, Technology Division, Health and Safety Executive

Dr Judy MacArthur Clark, Chairwoman, Farm Animal Welfare Council

Dr Linda Smith, Head of Biotechnology Safety Unit, DEFRA

## **E WRITTEN REPRESENTATIONS**

Advisory Committee on Releases to the Environment, *Statement on GM Animals*

Dr Luke Alphey, Oxford University

Vernon Barber, Food Science Adviser, National Farmers Union (later Policy Co-ordinator, Animal Science Group, UK Life Sciences Committee)

Peter Bradnock, British Poultry Council

Professor Donald Broom, Colleen McLeod Professor of Animal Welfare at Cambridge University and member of Animal Procedures Committee

Dr Donald Bruce, Society, Religion and Technology Project, Church of Scotland

Paul Carline, delegate to Edinburgh meeting

Professor Stephen Clark, Liverpool University and member of Animal Procedures Committee

Andy Coghlan, journalist, New Scientist

Joyce D'Silva, Compassion in World Farming

Dr Simon Festing, Association of Medical Research Charities

Edward Freemantle, Animal Health Trust

David Garwes, DEFRA

Professor Brian Goodwin, 'Scholar in Residence', Schumacher College, Devon

Dr Mae-Wan Ho, Director, Institute of Science in Society

Barbara Holgate, Director, Biological Services, AstraZeneca

Professor Tim Ingold, University of Aberdeen

Dr Ron James, PPL Therapeutics plc

Dr Jeff Kipling, Association of British Pharmaceutical Industries

Rudolf Kirst

Dr Judy MacArthur Clark, Chairwoman, Farm Animal Welfare Council

Dr Jim McKay, Aviagen

Dr Sue Mayer, GeneWatch

Graham Moore, Laboratory Animal Science Association

Dr Timothy Morris, Head of Animal Ethics & Welfare, GlaxoSmithKline

Janette Newton, Policy Research Officer, Research for Health, Association of Medical Research Charities

Diana O'Neill, delegate to Edinburgh meeting

Dr Vicky Robinson and Dr Martin Potter RSPCA

Professor Nancy Rothwell, MRC Research Professor, University of Manchester

Secretariat, Advisory Committee on Genetic Modification

Secretariat, UK Xenotransplantation Interim Regulatory Authority

David Whittaker, Huntingdon Life Sciences

## **ANNEX F**

### **WHAT THE WORDS MEAN**

This glossary gives definitions applicable in the context of this study; some terms may of course have different meanings in other contexts. Items in italics are defined elsewhere in the glossary.

<b>ACGM</b>	Advisory Committee on Genetic Modification
<b>ACRE</b>	Advisory Committee on Releases to the Environment: statutory body established under Part VI of the Environment Protection Act 1990, consisting of independent experts with a secretariat provided by <i>DEFRA</i> ; advises the Government on the safety of proposed releases and marketing of <i>GMOs</i> and non-native species, and on related issues
<b>AEBC</b>	Agriculture and Environment Biotechnology Commission: established in June 2000 following a review in May 1999 by Government of the regulatory and advisory framework for biotechnology with a remit to give Ministers independent, strategic advice on developments in biotechnology and their implications for agriculture and the environment
<b>APC</b>	Animal Procedures Committee
<b>BSE</b>	Bovine Spongiform Encephalopathy
<b>BST</b>	Bovine somatotrophin: a hormone produced by a GM micro-organism, which when injected into dairy cattle stimulates milk production, currently banned in the EU, but used in the USA and elsewhere
<b>Cartagena Protocol</b>	Protocol to the <i>CBD</i> on biosafety (signed in Montreal, January 2000)
<b>Carcinogen</b>	A substance which causes cancer
<b>CAWC</b>	Companion Animal Welfare Council
<b>CBD</b>	Convention on Biological Diversity
<b>Cloning</b>	Producing a cell or organism with the same nuclear genome as another cell or organism. In this report, 'cloning' means cloning by cell nuclear transfer, a method used in animal embryology in which the nucleus of one cell is transferred to another cell from which the nucleus has been removed. This technique has been used to produce cloned sheep and cattle. Molecular cloning is the process of replication of a single gene sequence, and may enable the production of genetically identical plants or animals. Cloned plants or animals are not necessarily also genetically modified.
<b>Commercialisation</b>	Producing livestock on a commercial scale, for the market
<b>Commission, the</b>	<i>AEBC</i>
<b>Conventional agriculture</b>	Commonly used in two different senses, to mean either agriculture not involving <i>GM</i> animals or non-organic agriculture
<b>DEFRA</b>	Department for Environment, Food and Rural Affairs (from June 2001)

<b>DETR</b>	Department of the Environment, Transport and the Regions (until June 2001)
<b>DNA</b>	Deoxyribonucleic acid, a molecule which comprises the genetic material of most living organisms
<b>DNA Vaccine</b>	A vaccine using a piece of DNA encoding a protein which induces an immune response instead of the protein itself. The foreign DNA is not expected to integrate into the host's genome and so the vaccinated animal is not genetically modified.
<b>EPA 1990</b>	Environmental Protection Act 1990
<b>EU</b>	European Union
<b>Eurobarometer®</b>	Survey of public opinion in the EU undertaken and published on behalf of the European Commission
<b>Expression</b>	As in gene expression: most genes are not active in all cells. If a protein is synthesised in a cell, the gene encoding it is said to be expressed e.g. insulin in the cells of the pancreas but not in many other tissues.
<b>FAWC</b>	Farm Animal Welfare Council
<b>FSA</b>	Food Standards Agency: established by Act of Parliament on 1 April 2000 with key functions including the provision of advice and information to the public and Government on food safety and protection of consumers through enforcement and monitoring
<b>Gene</b>	The basic unit of heredity; an ordered sequence of nucleotide bases, comprising a segment of DNA
<b>Gene flow</b>	The movement of genetic factors within and between populations.
<b>Genetic Biotechnology</b>	We use the term genetic biotechnology in the sense that it is the suite of techniques developed over the last two decades or so to augment traditional uses of <i>organisms</i> in plant and animal breeding. The most controversial of these techniques has been <i>recombinant DNA</i> , also referred to as <i>genetic modification</i> , <i>genetic manipulation</i> , <i>genetic engineering</i> and <i>transgenesis</i> and abbreviated to <i>GM</i> . We include <i>cloning</i> in the definition also in this report. <i>Marker-assisted breeding</i> and <i>mutation breeding</i> , and other technologies such as robotics (which are not considered in detail in this report), are outside the definition for the purposes of this report.
<b>Genetic engineering</b>	See <i>recombinant DNA</i>
<b>Genetic manipulation</b>	See <i>recombinant DNA</i>
<b>Genetic modification</b>	See <i>recombinant DNA</i>
<b>Genome</b>	The total set of <i>genes</i> carried by an individual or cell
<b>Genomics</b>	The study of <i>genomes</i>
<b>GM</b>	Genetically modified: see <i>recombinant DNA</i> and <i>GMO</i>
<b>GMO</b>	Genetically modified organism: defined as an organism in which the genetic material has been altered by the direct introduction of <i>DNA</i> (specifically defined in EU legislation)
<b>Knock in</b>	To insert genetic material into an organism's genome. It may be a complete new gene, or control sequences that will modify the production of a native gene.

<b>Knock out</b>	Removal of a gene by means of integrating genetic material into the gene so that the gene is rendered non-functional
<b>MAFF</b>	Ministry of Agriculture, Fisheries and Food (until June 2001)
<b>Marker assisted breeding</b>	Use of <i>marker genes</i> to enhance the conventional breeding of crops and livestock
<b>Marker gene</b>	A <i>gene</i> or short sequence of <i>DNA</i> that acts as a tag for another, closely linked, <i>gene</i>
<b>Micro-organism</b>	Usually a single-celled organism e.g. bacteria, yeasts, moulds and simple animals and plants
<b>Mutation breeding</b>	Selection of plants with natural or artificially induced (using irradiation or chemicals) mutations to produce novel varieties
<b>NGOs</b>	Non-governmental organisations
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>Organism</b>	An individual animal, plant, or single-celled life form
<b>Phylogenetically</b>	With reference to evolutionary development
<b>Procedure</b>	As in scientific procedures with animals: any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm
<b>RNA</b>	Ribonucleic acid; similar in structure to <i>DNA</i> , plays an important role in protein synthesis and other chemical activities of the cell. Many viruses are composed entirely of <i>RNA</i>
<b>Recombination</b>	The rearrangement of genetic material that occurs when <i>DNA</i> molecules are joined or exchange sequences with each other. It occurs during sexual reproduction and in some GM techniques.
<b>Recombinant DNA technology</b>	Experimental manipulation of <i>DNA</i> molecules using the techniques of molecular biology
<b>Risk assessment</b>	A tool for extrapolating from statistical and scientific data a value which people will accept as an estimate of the risk attached to a particular activity or event
<b>Selective breeding</b>	The use of organisms exhibiting desired characteristics to produce offspring which also bear these characteristics
<b>Self-cloning</b>	See <i>cloning</i> .
<b>Transgenesis</b>	The insertion of genetic material from one organism into another by recombinant <i>DNA</i> technology. The host and recipient may be of the same or different species.
<b>Transgene/transgenic</b>	Genes inserted by the direct incorporation of <i>DNA</i> , as opposed to endogenous genes
<b>UKXIRA</b>	UK Xenotransplantation Interim Regulatory Authority
<b>WTO</b>	World Trade Organisation
<b>Xenotransplantation</b>	The transplantation of tissue and organs between different species, and in particular the transplantation of animal tissue into humans.

## ANNEX G

### WHO WE ARE

#### HISTORY

The need for independent strategic advice on developments in biotechnology and their implications for agriculture and the environment emerged from the Government's review of the advisory and regulatory framework for biotechnology<sup>129</sup>. The main concerns expressed during wide consultation were that the current arrangements were complex and difficult for the public to understand, did not properly reflect the broader ethical and environmental questions and views of potential stakeholders, and were not sufficiently forward-looking for a technology which was developing so rapidly.

The Government concluded that the existing regulatory and advisory committees should continue to consider whether to grant approvals for individual products or processes, in the context of protecting the health of the public and protecting the environment. But there was also a need for a strategic framework for the overall development of the technology in the UK, to reflect the broader ethical and environmental concerns of society and to consider the future implications of biotechnological developments. The Agriculture and Environment Biotechnology Commission was set up to help provide this.

#### TERMS OF REFERENCE

The Commission's terms of reference state that it will:

- offer strategic advice to Government on biotechnology issues which impact on agriculture and the environment;
- liaise closely with but not duplicate the work of the other two bodies which together with the AEBC form a new strategic advisory framework i.e.:
- the Human Genetics Commission (HGC) which will advise on genetic technologies and their impact on humans; and
- the Food Standards Agency (FSA) which will include within its responsibilities all aspects of the safety and use of genetically modified food and animal feed;
- keep under review current and possible future developments in biotechnology with actual or potential implications for agriculture and the environment;
- advise Government on the ethical and social implications arising from these developments and their public acceptability; and
- consider and advise on any specific issues relating to relevant aspects of biotechnology as requested by the Government.

As part of this process the Commission is expected to:

- identify any gaps in the regulatory and advisory framework;

<sup>129</sup> Cabinet Office, Office of Science and Technology, *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review*, May 1999.

- consider the wider implications of the lessons to be learned from individual cases requiring regulatory decision;
- advise on any changes which should be made to Government guidelines which regulatory bodies are required to follow;
- make recommendations as to changes in the current structure of regulatory and advisory bodies;
- co-ordinate and exchange information with the relevant regulatory and advisory bodies;
- seek to involve and consult stakeholders and the public on a regular basis on the issues which it is considering; and
- operate in accordance with best practice for public bodies with regard to openness, transparency, accessibility, timeliness and exchange of information.

The Commission will:

- in carrying out its work take into account European and global developments;
- nationally, adopt a UK perspective taking appropriate account of legal and other differences between England, Scotland, Wales and Northern Ireland; and
- draw up a work programme.

The Government may also ask the Commission for advice on a particular issue and, if necessary, direct it not to become involved in an area if this could be better handled elsewhere.

NOTE: In the context of the work of the Commission, "Government" comprises the UK Government and the devolved administrations.

## COMMISSION MEMBERS

This report is agreed by the Commission as a whole. The work on the study was undertaken by the Animals and Biotechnology sub-group, whose members are denoted below by\*. A full list of members' declared interests can be found at [www.aebc.gov.uk](http://www.aebc.gov.uk).

### Chair

#### **Professor Malcolm Grant**

Pro-Vice-Chancellor at the University of Cambridge

### Deputy Chair

#### **Ms Julie Hill MBE**

Programme Adviser and former Director of Green Alliance

### Members

#### **\*Professor Michael Banner**

Professor of moral and social theology at King's College, London

#### **\*Ms Anna Bradley (Convenor of the Animals and Biotechnology sub-group)**

Director of the National Consumer Council

**\*Ms Helen Browning OBE**

Tenant Farmer, Eastbrook Farm; Founder and Director of Eastbrook Farm Organic Meats Ltd

**Dr David Carmichael**

Arable farmer with an interest in non-food crops

**Professor Philip Dale**

Leader of the Genetic Modification and Biosafety Research Group at the John Innes Centre, Norwich

**Dr Ed Dart CBE**

Chairman of Plant Bioscience Ltd

**\*Dr Matthew Freeman**

Senior Researcher at the Medical Research Council Laboratory of Molecular Biology

**Mr John Gilliland**

President of the Ulster Farmers Union and arable farmer with a particular interest in sustainable production systems and the pioneering of non-food crops

**Professor Robin Grove-White**

Professor of Environment & Society, and Director of the Centre for the Study of Environmental Change, Lancaster University

**Dr Rosemary Hails MBE**

Ecologist, and Principal Scientific Officer, Centre for Ecology and Hydrology Oxford and lecturer at St Anne's College, Oxford

**\*Ms Judith Hann**

A Freelance broadcaster and writer who presented Tomorrow's World for 20 years

**Ms ChiChi Iweajunwa**

Member of executive evaluation group for NHS Direct, and member of Partners Council for NICE (National Institute for Clinical Excellence)

**Dr Derek Langslow CBE**

Scientist specialising in nature conservation/biodiversity and former Chief Executive of English Nature

**\*Professor Jeff Maxwell OBE**

Former Director, Macaulay Land Use Research Institute

**Dr Sue Mayer**

Executive Director of Genewatch UK

**\*Professor Ben Mepham**

Director of the Centre for Applied Bioethics at the University of Nottingham and Executive Director of the Food Ethics Council

**Ms Justine Thornton**

Barrister specialising in environmental law

**Dr Roger Turner**

Chief Executive Officer, British Society of Plant Breeders

## **ANNEX H**

### **CONTACT US**

The AEBC is keen to receive feedback on its work and also to receive information about further developments.

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