This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

RSPCA Response to Nuffield Council on Bioethics 'Emerging Biotechnologies' Consultation Paper (April 2011).

This submission summarises the RSPCA's concerns about the impact that emerging biotechnology has, or is likely to have, on animals and their welfare. It focuses on biotechnology applications in human and animal health and agriculture, and the effects of such applications on the lives and welfare of laboratory, farm, companion and wild animals.

Our concerns are based on the fact that some of the developments and applications of emerging biotechnology:

_ involve procedures that may cause animals pain, suffering or distress;
_ use a very large number of animals;
_ encourage a wider variety of applications leading to increased animal use;
_ increase the perception of animals as commodities for human use and/or gain, such as research tools or units of production;
_ are progressing at a rate that is outstripping public understanding and ethical and public debate.

Q1 How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

'Biotechnology' has been defined by others as "*the application of science and technology to living organisms, as well as part, products, and models thereof, to alter living, or non-living materials for the production of knowledge, goods and services*" (OECD Biotechnology Statistics 2006, Paris). This seems a good definition. Our concerns and responses relate to any aspect of this definition of 'biotechnology' that has, or might have, an impact on animal welfare. For the purposes of this consultation we have also define 'emerging' as any new, or novel use/application of an existing biotechnology and so all subsequent questions have been answered within this context.

Q2 Do you think that there are there features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

We believe three of the points listed in our introductory statement are common to the biotechnologies that concern us, they:

_ encourage a wider variety of applications, leading to increased animal use;
_ increase the perception of animals as commodities for human use and/or gain, such as research tools or units of production;
_ are progressing at a rate that is outstripping public understanding and ethical and public debate.

Q3 What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

The biotechnologies that we are currently most concerned about are:

 the creation of genetically manipulated (GM) and cloned animals;
 the subsequent use of these animals:
- as disease models;
- in fundamental research e.g. to understand gene function;
- in toxicity testing;
- for food production;
- as 'bioreactors' to produce biologically active compounds for experimental and/or medical purposes;
- as sources of cells, tissues and organs in xenotransplantation;
- in the creation of cloned pets, sports animals and 'living art'.

However, any emerging biotechnology that is developed and/or tested in animal models, or that causes the animals pain, suffering, distress or lasting harm is of serious concern to us. Examples include tissue engineering, the nanotechnology, and stem cell research.

Q4 Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?

We have no comment to make.

Q5 Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?

We have no comment to make.

Q6 Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

Yes, the 2008 US FDA risk assessment on animal cloning has had a profound impact on the revision of the European Novel Foods Regulation (EC258/97). The FDA risk assessment concluded that meat and milk from cow, pig, and goat clones and the offspring of any animal clones are as safe as existing food products. This paved the way for such food products from cloned animals to be exported to countries including EU Member States without prior approval, or labelling. Since then the European Commission (EC) has failed to reach agreement on how to revise the European Novel Foods regulation and therefore how it regulates novel food products, which includes those from cloned animals, should be approved. However the EC is ambiguous about how food products from the offspring of cloned animals are approved and labelled. The reason given for this failure to reach agreement is that there is a potential threat of World Trade Organisation (WTO) action against Europe if a decision is taken to ban the import of food products from cloned animals or their offspring, despite this being the opinion expressed by the European public and the European parliament.

Q7 How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?

We have no comment to make.

GENERAL

Q8 Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

There are ethical issues, but the majority of these are not specific to emerging biotechnologies. These include:

- *Numbers of animals used*

  Use of animals in experiments is a matter of serious public concern and pressure to reduce numbers has contributed to a downward trend in some countries. Creation and use of GA animals is reversing this trend and there has been an exponential rise in the number of GA animals used in scientific procedures each year in some EU member states. For example, in the UK, the number of GA animals has risen from around 50,000 in 1990 to 900,000 in 2004 (Home Office Statistics 1990-2004). In Germany, Ireland, Finland, Sweden and the Netherlands, there is also increasing creation and use of GA animals (EU Stats 1999, 2002).

  GA animals can be produced by a number of different techniques, all of which are inherently wasteful with respect to the number of embryos that are manipulated relative to the number of GA offspring subsequently produced. Estimates suggest only a 3-5% success rate when generating new GA animals (e.g. Nuffield Council on Bioethics, 2005). The remaining offspring are surplus to requirements and are killed. A large number of animals are therefore used to provide sufficient eggs or embryos for genetic manipulation, and to act as recipients and foster mothers for the manipulated

embryos. These animals will usually be killed, either before harvesting the eggs or embryos, or, in the case of recipients, once their young are weaned. Thus GA technology is wasteful of animal life and the ethical implications of such wastage are important and need to be acknowledged.

- *Potential for pain, suffering or distress during creation of GA or cloned animals*
  The procedures used to produce GA and/or nuclear transfer cloned animals involve hormonal and surgical interventions that can cause pain, suffering and distress. These include; superovulation, vasectomy, semen and embryo collection and embryo transfer (JWGR, 2003; Pew Initiative, 2002).
  Many of the manipulated embryos die during gestation. This may also cause suffering, although this depends on the stage of development at which death occurs and the species involved.

- *Adverse effects as a consequence of genetic alteration and cloning*
  Where GA animals are created as models of specific diseases, they can experience a range of adverse effects associated with the condition in question, which can have profound effects on their health and welfare. However, being genetically altered does not necessarily compromise the welfare of individual animals, and indeed some GA animals are indistinguishable from their non-GA siblings. It also needs to be acknowledged that adverse effects may only become apparent when animals are subsequently maintained in a less well defined or controlled, environment than that of the laboratory or experimental farm. Nevertheless, in many cases, genetic alteration can have a deleterious effect on animal welfare and the harms caused depend on a number of factors.

  Studies have shown that some *in vitro* culture procedures carried out during genetic manipulation or cloning protocols can lead to unpredictable complications in the animals subsequently produced (ECVAM, 1998). An example of this is Large Offspring Syndrome (LOS), which affects sheep, mice and cows following nuclear transfer. As well as causing complications for the mother during birth, LOS encompasses a range of debilitating pathologies for the offspring including malformations in the liver, brain and urogenital tract, immune dysfunction, placental abnormalities, stillbirth, fetal overgrowth, respiratory failure and circulatory problems (Vajta and Gjerris, 2006).
  A further concern is that there is currently no mechanism to ensure consistency in the training of personnel in specific GA technologies and procedures, or to ensure that experimental and other refinements are disseminated throughout the biotechnology community. This can have a profound influence on the levels of pain, suffering and distress experienced by animals undergoing these procedures. It can also have a negative impact on the success rates achieved and levels of animal wastage.

- *Concerns regarding mutagenesis programmes*
  Mutagenesis (using chemicals such as ENU, or physical mutagens such as radiation, to increase the natural mutation rate of DNA) is the quickest method for producing large numbers of GA mice. This technique is being widely applied both in Europe and beyond, with mutagenesis programmes aiming to explore the function of every gene in the mouse genome. This project presents a number of animal welfare concerns:

- the number of animals involved in mutagenesis programmes is vast; e.g. around 35-36,000 for a 3 year project, or around 50 animals per mutant line established (Mammalian Genetics Unit, Harwell, 2006);
- the process of mutagenising animals has significant animal welfare implications for the animals involved, for example males require 12-14 weeks to recover their fertility following treatment with a mutagen. Furthermore, only around 50% of mutagenised males are able to go on to sire offspring with the remainder being culled (Goldwitz et al, 2004);
- the mutations induced are by their very nature unpredictable and the scientific usefulness of mutagenised animals cannot therefore be predicted, nor can the effect of any mutation on the health and welfare of the animals. This makes the justification for producing GA mice in this way highly questionable.

- *Concerns regarding knockin and knockout technology*
  A more targeted approach to the production of GA animals uses DNA constructs inserted into the animals genome to either completely remove a gene of interest (knock-out), or to replace a given gene with an altered version (knock-in). This is done either in the whole animal, or within specific tissues of an animal (conditional). The animal welfare concerns include:

- at the current level of efficiency, the numbers of animals used is high - at least 200 animals will be used in the production of a single GA mouse (Mammalian Genetics Unit, Harwell, 2006);

- the site of insertion into the host genome and the number of copies of the DNA construct inserted cannot always be controlled unless ES cell manipulation is used. This can be a problem because the incorporation of the construct DNA at an incorrect location can result in the random inactivation of other genes or alterations in the expression of surrounding genes, both of which can impact on the health and welfare of the animals produced;
- when a knockout animal is generated the level, or pattern of expression observed for other genes can be altered to compensate for the lost gene (Okkenhaug, 2003). Thus any effects observed in the GA animal may not only reflect the loss of the gene of interest, which means that investigation of the effects is not always straightforward. The use of knock-out as an alternative to knock-in or conditional technology, therefore needs careful consideration and justification.

- *Special concerns for non-human primates*
  This submission relates to <u>all</u> animals used in biotechnologies, but the RSPCA has particular concerns about the application of such technologies to non-human primates. Macaques have already been cloned by nuclear transfer in the USA (Chan et al, 2001), and recent technical advances mean that the production of GA primates is a realistic possibility in the foreseeable future. The RSPCA firmly believes that the genetic modification of non-human primates should not be allowed for any purpose, given the ethical issues raised by such developments, the large number of animals required to produce each GA animal, and the associated potential for harms.

- *Concerns regarding animal models of disease*
  A common justification for the creation of GA animals is that they will provide, or contribute to, 'improved', more predictive models of disease. This is an oversimplification because a) this is not necessarily always true, and b) even where a new GA model is more appropriate, it is commonly used alongside other, older models. There is no mechanism for ensuring only the most relevant are used and that newer models are available to all researchers where these would genuinely improve scientific quality and/or translatability. In such cases the GA animal is not the new *definitive* model but just an *additional* one. The motivation for the research may merely be an interest in the model for its own sake, but a medical application may be used to justify the work since this is likely to be more acceptable publicly and politically.
  There is also currently no requirement for GA animals to be cryopreserved and stored within central archive facilities or depositories. Such methods can reduce repetition and duplication of work by providing a central resource for use by the wider scientific community and protect against adverse events such as environmental disasters or genetic drift. They also reduce the need for live transportation of GA animals, with associated welfare problems, because frozen gametes or embryos could be sent instead.

- *Concerns regarding GA animals in toxicity testing*
  GA mice and rats are increasingly used in genotoxicity and carcinogenicity testing, within studies that are done to fulfil regulatory requirements for the marketing of chemicals and pharmaceuticals. Such animals are likely to suffer equivalent (or even more severe) levels of pain and distress to those experienced by animals in traditional tests, but it has been claimed that fewer animals will be needed.
  The RSPCA believes that reducing the numbers of animals used in research and testing is an important goal, provided that this can be done without increasing the level of suffering experienced by individual animals. However, relatively severe adverse effects have been reported in some GA strains used in toxicity testing (ECVAM, 1998). For example, mortality rates are higher in *c-neu* and *c-myc* mice used in carcinogenicity testing than in conventional mice used in the same type of test. Many GA mice used in carcinogenicity tests are more susceptible to developing cancer and so will develop tumours more rapidly, which could make it more difficult to implement humane endpoints. Reducing numbers is thus not automatically a positive outcome for animals - the impact on individuals must be taken into account and it may be justifiable to use more animals who will suffer less.
  In any case, the contribution that biotechnologies can make to reducing animal numbers in carcinogenicity and genotoxicity is not consistent, largely due to actual or potential regulatory requirements. For genotoxicity testing, GA models have distinct scientific advantages over existing *in vivo* assays when used as second tier tests for *in vitro* genotoxins. The reduction in numbers of animals used would be fairly substantial, perhaps from 50 to 20 per substance tested, but again it is not certain that a test on one GA model would be regarded as sufficient. There are potentially much greater savings in animals if GA tests can be used in place of very large tests of heritable mutation which are currently used, albeit rarely, for chemicals of high concern.

Conversely, using GA animal models in toxicity testing could increase the use of animals by making some tests more practical, or by increasing the amount of information they produce. For example, the use of GA animals could make investigations feasible that would otherwise require very large and impractical numbers of non-GA animals. Regulators might be inclined to ask for the GA test in cases where the conventional test would not have been requested (and could therefore presumably have been done without) because it was regarded as too cumbersome and possibly uninformative.
The RSPCA believes that, in toxicity testing as in the other research fields, the focus should be on developing *in vitro* alternatives to replace animals and not on developing different animal models.

- *Concerns regarding GA animals for food production*

The selective breeding of farm animals has been conducted for thousands of years, and has given rise to a number of welfare concerns. However, the RSPCA believes that the use of biotechnologies to speed this process, or to introduce genes that could never be incorporated into the genomes of farm animals by any natural process, is a serious ethical and welfare issue. Directly altering an animal's genome is viewed by many as an unacceptable assault on the integrity of the animal that is incompatible with the concept of respecting farmed animals, and minimising the harms that are caused to them for human benefit. These views are important and should be respected as a legitimate part of the debate on biotechnology.

The RSPCA also questions the necessity of further increasing production in farm animals. In many cases, productivity is already pushing animals to their physical and metabolic limits, so with any further increase there is an enhanced likelihood of animal welfare problems. Enhancing selective breeding, by gene mapping or genetic alteration, can also cause suffering if the trait that is selected for has a negative impact on the rest of the animals' physiology. For example, hens who produce high numbers of eggs suffer from osteoporosis because the majority of the calcium they ingest is used in eggshell production (J. Mench, Pew Initiative, 2002). Farmed species have also had the composition of milk, meat and meat quality or quantity including the proportion of lean meat to fat altered. For example, pigs and cows respectively have been genetically altered to have higher levels of Omega 3 in their muscle (Lai et al, 2006), and to express higher levels of casein in their milk (Brophy et al, 2003). This is now being taken a step further with 'prize' animals being cloned in order to standardise the quantity and/or quality of the food products they produce with the aim of reducing financial costs. Such practices only increase the perception of animals as units of production, or commodities for human use and are progressing primarily because the technology exists, rather than because there is a genuine need for food to be produced this way. The RSPCA is completely opposed to the cloning of animals for food production purposes and many of these applications of biotechnology are progressing at a rate that far exceeds public knowledge or understanding. More importantly these applications are progressing without consideration for whether the public needs or will accept food products produced in this way.
Animals are also genetically altered to be resistant to disease, for example, cattle have been engineered to express the antibiotic lysostaphin in their milk, which results in increased resistance to mastitis (Wall et al, 2005). Pigs, sheep, mice and rabbits have also been modified to express antibodies providing immunity to specific diseases (Lo et al, 1991; Weidle et al, 1991), for example mice have been generated with protection against prion disease (Heppner et al, 2001). Whilst there may be some potential animal health or welfare benefits to these genetic alterations, their existence may also encourage the keepers of the animals to take less care of them, or check them less frequently leading to other potential animal health, or welfare problems arising. For example, clinical mastitis is a major welfare problem in dairy systems with sub-optimal standards of hygiene, and early detection is reliant on routine inspections by parlour staff at milking. The creation of cattle resistant to mastitis may encourage the perception that mastitis is no longer a problem. This could not only compromise standards of parlour hygiene, but may reduce the level of attention paid to each animal at milking. This would increase the potential for other clinical or welfare problems to go undetected.

Animals have also been genetically altered to reduce their environmental impact. For example the 'Enviropig™', has been engineered to contain the enzyme phytase in the pigs' saliva so that they can digest sources of dietary phosphorus. This results in faeces with a lower phosphorus content, which in turn reduces the pollution of surface and ground water with phosphorus (Golovan et al, 2001).

Regardless of the type, or nature, of the genetic alteration these animals experience, it is true to say that very few studies have examined the health and welfare status of genetically altered or cloned

animals and/or their offspring throughout their entire birth to death experience. Similarly, there is not a wealth of information regarding the transition of such animals from the laboratory to the less controlled environment of a farm, or human home. It may be possible for genetically altered or cloned animals to be properly managed and cared for in the controlled environment of a breeding company or experimental farm, but there are serious concerns regarding the welfare of such animals once they are released into commercial agriculture.

- *Concerns regarding animals as 'bioreactors'*
  This category of GA animal use includes:

  - "pharmed" animals who produce therapeutic substances e.g. pigs who express the blood protein Factor IX in milk, and goats that express the anti-clotting agent Atryn in their milk (Van Cott et al, 1996; Lindsay et al, 2004; GTC Therapeutics);
  - animals producing specialist materials e.g. goats who produce spiders' silk proteins in their milk for use to make 'biosteel'. This has both medical and non-medical applications (e.g. in sutures and bullet-proof vests respectively) (Nexia Biotechnologies, Quebec);

  The substance produced may have an adverse effect on the animal, either at the point of expression, or if it can enter the animal's bloodstream. For example, a strain of rabbits genetically engineered to express human erythropoietin (EPO) in the mammary glands also expresses the protein at low levels in other organs, resulting in greatly elevated numbers of red blood cells, infertility and premature death (Massoud et al, 1996). Using animals in this way, and referring to them as 'bioreactors', reinforces the perception of animals as units of production and/or biological tools, rather than as sentient beings with the ability to experience pain, suffering and distress.

- *Concerns regarding Xenotransplantation*
  The use of GA animals to supply organs, tissues or cells for transplantation into humans is a highly controversial issue which has been the subject of a great deal of debate. There are many legal, scientific, human health, animal welfare and ethical concerns, which have been described in a number of documents (Nuffield Council on Bioethics, 1996; Kennedy Report, 1997; Council of Europe, 2002). Only the ethical and welfare issues relating to animals are addressed here. These include:
  - the ethics of genetically altering animals of any species as a source of cells, tissues and organs for human transplantation;
  - the harms associated with the initial creation of GA animals as source animals (see section 2.1);
  - the suffering and/or distress associated with production and maintenance systems for high health status source herds. This includes hysterotomy-derivation, early weaning practices, and barren husbandry environments, which have a serious negative impact on animal welfare because they prevent animals from satisfying their physical, social and behavioural needs.

  Furthermore, development of 'xeno' technology to a point where it can be used still requires a great deal of pre-clinical research. To date, such research has included studies of efficacy, physiology, immunology, and infection risks in a range of species including primates, goats and dogs. This research, by its very nature, causes considerable suffering. Experiments involving organ transplantation require major surgery, which in itself causes suffering that is exacerbated by tissue rejection and immunosuppressive treatment.

  Xenotransplantation is also an example of a biotechnology where over-optimistic claims are made to justify the approach, the funding and the use of animals. This raises false hopes for patients and we believe this is unethical. For example, in September 1995, the UK company Imutran *"envisaged the first xenotransplants of transgenic pig hearts into human patients taking place in 1996"* (Nuffield Council on Bioethics, 1996). Yet despite some progress, particularly with cell transplants, the transplant of whole organs is no closer and xenografts still rarely survive for more than a few months (Chapman, 2004).

- *Concerns regarding cloning companion animals, sports animals and 'animals as living art'*
  The RSPCA believes that, without doubt, some applications of modern biotechnology are trivial, scientifically unnecessary and ethically unjustifiable. Examples include;
  - the cloning of champion racing and show jumping horses for sport (Galli et al, 2003; Cryozootech);
  - the generation of a green fluorescent rabbit 'GFP Bunny' as transgenic "art" (Eduardo Kac, 2000);

- the cloning of companion animals for example cats, purely to satisfy humans' emotional requirements (Shin et al, 2002; Genetic Savings and Clone Inc).

Q9 Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

Ethical and animal welfare concerns may be mentioned during discussions about emerging biotechnologies, but they are commonly dismissed if there are no specific scientific or human safety concerns. This is because the animal welfare concerns are either not recognised, or not thought to be sufficiently important because of a lack of evidence, or data with statistical significance. This is illustrated by European Commission appearing to ignore the comments of the European Group on Ethics in Science and Technology report on the '*Ethical aspects of animal cloning for food supply*' (2008), and the presentation of these issues in the '*EFSA Scientific Opinion on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from cloning by SCNT and their Offspring and Products obtained from those animals*' (2008).

Discussions regarding biotechnology that we have participated included in rarely involve questioning the justification for the specific application of the biotechnology in question, or any weighing of the harms to animal health and welfare versus the potential benefits of the application in question. Similarly little or no thought is given to any requirements for safety or efficacy tests that may be generated by new applications of biotechnology, some of which involve tests that cause pain, suffering or distress to animals. Ethical and welfare issues associated with the patenting of animals and the creation of chimerias have been investigated in the past, but rarely are these issues given the consideration and weight that they deserve.

Q10 What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?

Ethical and social issues have not always effected decisions when we believe they should have done. All too often it seems that biotechnologies and their applications are developed because advances in science make them possible, rather than because there are specific needs or public desire for them. The RSPCA is extremely concerned that the application of all biotechnologies is advancing at a rate that far outstrips public understanding and knowledge.

ETHICS

Q11 What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?

The principles of ethical review including weighing potential harms and benefits - should be applied, with input and discussion from people with a diverse range of expertise and perspectives, including adequate lay and animal welfare representation. There should be a critical assessment of the actual need, and/or justification for the emerging biotechnology. These principles should apply to all relevant fields, not just human or animal health research and agriculture. If it is determined that a particular application is necessary and justified, any pain, suffering or distress should be reduced to an absolute minimum, throughout the entire lives of all the animals involved. Every effort should then be made to ensure the benefits are maximised and applied.

Q12 Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised? Need to think.

See answer to question 11. Decisions should be well informed and made after discussion with people from a diverse range of expertise, interests and perspectives. The process should be open and transparent, so that the public can be satisfied that there are adequate controls on the application of biotechnology and that their views have been taken into account and respected.

POLICY

Q13 What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

'Risk' and 'precaution' only seems to be applied to safety issues, however both are also very relevant to animal health and welfare concerns.

Q14 To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

Biotechnology is too diverse to regulate under a single framework, as the harms, benefits and the fields in which these technologies are applied can vary widely. Separate bodies with relevant expertise would be more appropriate and effective, provided that the interests of animals and their welfare are properly represented as outlined above. However, it is also essential for there to be 'joined up thinking' between different regulations and regulatory bodies, which would require a framework for coordinating these, possible in the form of an overarching body that would facilitate communication and consistency. For example, principles enshrined in animal welfare legislation such as the 'Three Rs' and 'Five Freedoms' should be consistently applied to any other regulation that involves animal use or impacts on animals in other ways.

PUBLIC ENGAGEMENT

Q15 What role should public opinion play in the development of policy around emerging biotechnologies?

We believe that public opinion should play a fundamental role in the development of policy around emerging biotechnologies. Huge numbers of animals are commonly used within biotechnologies and these lives will be wasted if there is no public interest in the outcome, or support for the processes or products that have been created.

Q16 What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?

Any public engagement activity on a topic relating to biotechnology will inevitably have to overcome some prejudices resulting from media coverage of previous developments. Surveys may be useful as a means of gauging immediate public reactions, but in the RSPCA's view an approach of the type taken by the Academy of Medical Sciences (AMS), when evaluating public opinion on the use of animals containing human material, can lead to more comprehensive responses and better guidance on policy issues. The AMS surveyed the public, but also aimed to set up a deeper dialogue through deliberative workshops, focus groups, and interviews. This presents opportunities for people to think beyond their more immediate responses, inform their views on the harms, benefits and applications of biotechnology, and help to provide sounder guidance with respect to what society would find acceptable and why.

However, the RSPCA believes that full, honest and well informed appraisals of the ethical and animal welfare implications of biotechnologies are an essential component of any public engagement activity.

Q17 Is there something unique about emerging biotechnologies, relative to other complex areas of government policy making, that requires special kinds of public engagement outside the normal democratic channels?

In our experience, biotechnologies that have the potential to cause animals pain, suffering, distress or lasting harm do not do so in any 'new' ways. That is, the suffering that can be caused to those animals directly or indirectly involved in the application of biotechnology does not differ, in nature or level, from suffering that may be caused by scientific procedures, agricultural practices or any other current human-animal interaction.

The differences with biotechnologies that may require 'special' engagement with the public are that:

- it can be more difficult to predict the nature and/or level of suffering, as these are new technologies;
- many people have beliefs that make them especially concerned about the application of biotechnologies, and their concerns should be properly explored and given due respect.