

# GENETIC MANIPULATION OF ANIMALS IN RESEARCH

## Current situation

Genetic manipulation involves the deliberate modification of an animals' genome - its DNA - the material that codes for inherited characteristics. It is either copied, added to, deleted or edited and includes both genetically modified (GM) as well as cloned animals.

The range of species that have been genetically manipulated is expanding alongside the fields of research in which these animals are used. Current applications include:

- Models for basic fundamental research to understand gene function.
- Models of human or animal disease.
- Bioreactors to produce therapeutic proteins in milk or blood.
- Sources of tissues or organs for xenotransplantation.
- Livestock with improved production traits and, or disease resistance.
- Better subjects for vaccine and toxicity testing.

There are specific welfare and ethical concerns associated with the genetic manipulation of animals. In addition, the pace of scientific developments in this area of research often outstrips meaningful ethical debate. The crossing of boundaries between species and human interference with the genetic integrity of animals has also evoked strong moral objections.

## Welfare Concerns

**Genetic modification (GM)** - Laboratory use of GM animals is increasing dramatically. Within the EU statistical comparison of figures on GM animal use is not available, but where GM animals numbers are recorded by member states they are generally increasing. For example, over the last ten years there has been a shift ongoing from other species to the use of GM mice<sup>78</sup>. In the UK, GM animals also account for one third of all procedures<sup>79</sup>.

GM animals are created using:

1. Gene targeted methods, where the DNA within a specific gene of interest is modified in some way, and
2. Non-gene targeted approaches such as mutagenesis - a method used to create completely random mutations in DNA.

<sup>78</sup>/Commission of the European Communities (2010) Sixth report from the Commission to the Council and the European Parliament on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 2008) CEC, Brussels.

<sup>79</sup>/Home Office (2006) Statistics of Scientific Procedures on Living Animals -Great Britain 2005: The Stationary Office, London.

Ethical and welfare concerns that apply to the production and use of GM animals include:

- The requirement to use large numbers of animals to both create and breed GM animals because current methods are inherently inefficient and wasteful of animals' lives.
- Specific procedures are used that are highly invasive or require surgery (depending on species), such as the transfer of modified embryos into recipient animals, that can cause pain, suffering and distress.
- Genetic modification can alter the characteristics of an animal in ways that can cause pain, suffering, distress, or lasting harm. When using non-gene targeted methods these effects can be especially difficult to predict.
- Many GM animals are 'born to suffer', for example if they have been genetically modified to create an animal model of a disease.
- Some GM animals experience a poor quality of life such as animals used in toxicology studies, or as a source of xenotransplant organs. They are often housed in pathogen free environments that may be relatively barren and do not provide for their complex behavioural and social needs.
- GM animals are viewed within science according to their value as biological tools, rather than as sentient beings with intrinsic value and the capacity to experience pain, suffering and distress.
- GM animal use in research and testing seems set to continue to grow, reversing what was a downward trend in the use of animals.

### **Cloning**

Cloning involves taking DNA from an existing animal (dead, or alive) to create a new living animal with the same genes. Species that have been cloned to date include sheep, mice, cattle, horses, cats, monkeys and goats. Cloning is thought to have some potential in creating standardised livestock animals for food production and in creating copies of sports animals, or pets.

Cloning raises a number of animal welfare issues in addition to those mentioned above for GM animals such as:

- A large proportion of animals produced by this technology die shortly after birth as a result of physiological problems and other abnormalities.
- Many cloned livestock animals at the time of birth are much larger than traditionally bred animals, which can make giving birth extremely difficult and which may necessitate caesarean section delivery.
- The long-term effects of cloning on animal welfare are unknown. However, there is evidence that some cloned animals experience a reduced life-span in comparison with non-cloned animals, and that all animal clones are more likely to suffer from a range of abnormalities, including tumours, liver disease, pneumonia and disorders of the immune system.

## **Relevant legislation**

Council Directive 86/609/EEC – currently under revision - regulates the use of animals for experimental and other scientific purposes. It transposes into EU legislation the Council of Europe Convention ETS 123 (1986), which covers all aspects of animal use in research, including fundamental research. However Directive 86/609 covers only those animals used in experiments for safety testing and protection of the environment and neither makes specific reference to genetically manipulated animals.

Council Directive 98/58/EC (1998) covers the protection of animals kept for farming purposes. It gives no specific mention to genetically manipulated animals but does state that "*natural, or artificial breeding, or breeding procedures which cause, or are likely to cause suffering or injury to any of the animals concerned must not be practiced*" (Annex, point 20). Similarly point 21 of the Annex states that "*no animals shall be kept for farming purposes unless it can reasonably be expected, on the basis of its genotype or phenotype, that it can be kept without detrimental effect on its health or welfare*".

## Genetic modification

Two different pieces of legislation specifically reference genetic modification:

- *Directive 2001/18/EC (2001) on the deliberate release into the environment of genetically modified organisms* (this repealed Directive 90/220).
- *Regulation (EC) No 258/97 (1997) concerning novel foods and novel food ingredients* (currently being revised)

Directive 2001/18/EC covers aspects concerning the release of a GM organism into the environment, risk assessments, traceability and labelling. It does not cover the welfare of released GM organisms. Similarly Regulation (EC) No 258/97 applies to food and food ingredients containing, or consisting of genetically modified organisms, but not the source (animal or plant) of such food, or food ingredients.

## Action needed

- Policies, guidelines and legislation must be developed to ensure that techniques to genetically manipulate animals are only applied where there is very strong justification and when the use, suffering, and wastage, of all the animals involved is minimised. More specifically such policies must clearly state that primates should not be genetically manipulated for any purpose and that other animal species should not be genetically manipulated for the following purposes:
  - to create any genetically modified animal whose suffering will not, or cannot, be alleviated;
  - to clone or genetically modify animals for the purpose of food production;
  - to create cloned or GM animals for use as companions, or for other trivial purposes, e.g. the glowing rabbit that was created as a “work of art” and cloning sports animals and pets;
- Greater consideration must be given to an animal’s capacity for suffering, the likelihood of suffering occurring and how that suffering will be alleviated before GM animals are created.
- Greater public understanding and debate – link to Commission Action Plan and their stated aim to ensure a better informed public in relation to science and technology.